EPA Registration No. 82012-3 vol. 1

Material to be added to an e-Jacket/Jacket

Reg. No. 82012-3

1. ☑ **Placement within the e-Jacket/jacket:**
   - ☐ **Default: (chronological, top/newest)**
   - ☐ **Description: (PDF page number, i.e., "before page 45")**

_____

_____

2. ☐ **Send to Data Extraction contractors this material:**
   - ☐ **Newly stamped accepted label**
   - ☐ **Notification**
   - ☐ **New CSF**
   - ☑ **Other:** Amendment

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: K Leavy

Phone: _____ **Division:** AJ

Date: 2/10/11

Created July 21/2008

DECISION PKG. NO. 440114 SUBM. DUE DATE 2/13/11

SUBMISSION BAR CODE # 882644 REVIEWER ICL

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDME

FILE SYMBOL/REG NO: 82012-3 PM 33 ACTION CODE 450 **PRIA**

DESCRIPTOR Amendment **FQPA** **NFQPA**

[ ] CHILD RESISTANT PACKAGING: [ ] REQUIRED [ ] NOT REQUIRED

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL [ ] RESTRICTED US

DATE ON APPLICATION	EPA RECEIVE DATE	PM RECEIVE DATE
9/20/10	9/22/10	9/22/10

METHOD OF SUPPORT

[ ] CITE-ALL [ ] SELECTIVE
[ ] NOT SUBMITTED [ ] N/A

FORMULATORS EXEMPTION

[ ] SUBMITTED [ ] NOT SUBMITTED
[ ] N/A

REVIEW(S) REQUESTED	DATA PACK #	DATE SENT	DUE DATE	DATE RETURNED
CHEMISTRY				
EFFICACY				
ACUTE TOX.				
RASSB TOX.				
ENVIRON. FATE				
FISH/WILDLIFE				
OTHER:				

STATUS

RESPONSE CODE 1165 RESPONSE DATE 2/10/11

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

FEB 10 2011

Ms. Heather R. Bjornson
Regulatory Assistant for,
Copper Development Association
260 Madison Avenue
New York, New York 10016

Mail to: Heather R. Bjornson
Technology Sciences Group, Inc.
1150 18th Street, N.W.
Suite 1000
Washington, D.C. 20036

Subject: Antimicrobial Copper Alloys Group III
EPA Registration Number 82012-3
Your Amendment Dated September 20th, 2010
EPA Received Date September 22nd, 2010

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to add additional alloys to the product formulation, is acceptable.

The Confidential Statement of Formula dated January 5th, 2011, for the basic formulation is acceptable.

The Confidential Statement of Formula and product labeling have the same nominal concentration.

The updated product chemistry data has been reviewed and found to be acceptable.

The Agency has no human health concern over the active ingredient in the six registered Antimicrobial Copper Alloy Groups, i.e., the metallic copper. Also, the Agency has no human health concern for any of the intentionally-added inert ingredients at the revised concentrations proposed in the 01/05/11 Confidential Statements of Formula for the six products.

If you have questions concerning this letter, please contact Karen M. Leavy at (703)-308-6237.

Sincerely,

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of Pesticide Programs

Antimicrobials Division (AD)

January 11, 2011

DP BARCODE:	D382757	
MRID:	482363-01	
SUBJECT:	Antimicrobial Copper Alloys – Groups III	
REG. NO. OR FILE SYMBOL:	82012-3	
DOCUMENT TYPE:	Product Chemistry Review	
Manufacturing-use [] OR	End-use Product [X]	
INGREDIENTS Copper	(PC Codes) (022501)	CAS Number: 7440-50-8
TEST LAB:		
SUBMITTER:	Copper Development Association	
GUIDELINE:	830.1750	
COMMODITIES:	Formulation	
REVIEWER:	Juan F. Negrón	
ORGANIZATION:	AD	
APPROVER:	Karen P. Hicks	
APPROVED DATE:	01/11/11	
COMMENT:		

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

January 11, 2011

MEMORANDUM

Subject:	Product Chemistry Review for EPA Reg # 82012-3. Antimicrobial Copper Alloys – Groups III DP# 382757
From:	Juan F. Negrón, Chemist Product Science Branch, CT Team Antimicrobials Division (7510P)
Thru:	Karen P. Hicks, CT Team Leader Product Science Branch Antimicrobials Division (7510P)
To:	Marshall Swindell / Karen Leavy PM Team 33
APPLICANT:	Copper Development Association
Action code:	A570
Due date:	02/13/11

Product Formulation from label
Active Ingredient

	% by wt.
Copper	82.6

BACKGROUND:

On behalf of the registrant, Copper Development Association, Inc., the consultant, Technology Sciences Group, Inc., has submitted an amendment to add additional alloys. The product, "Antimicrobial Copper Alloys – Group III," is an integrated end-use product. The Product Chemistry Reviewer has received the following documents:

- A letter dated 09/20/10. MRID # 482363-00.
- Transmittal document, dated 09/20/10.
- Confidential Statement of Formula (CSF), dated 09/20/10 & 01/05/11, for the basic formulation.
- Study titled "Antimicrobial Copper Alloys Group III Product Properties – Group A" Volume 2 of 2. MRID #482363-01.

FINDINGS:

1. The CSF, dated 09/20/10, for the basic formulation is obsolete.

2. The CSF, dated 01/05/11, for the basic formulation is revised.

3. The CSF and the label have the same nominal.

4. The registrant updated the OPPTS 8360.1750 Certified Limits Guideline.

5. The registrant updated the study, dated 01/05/11, titled "Antimicrobial Copper Alloys Group III Product Properties – Group A" Volume 2 of 2. MRID #482363-01 for consistency with the CSF.

CONCLUSION:

The CSF, dated 01/05/11, for the basic formulation is acceptable. The MRID # 482363-01 is partially acceptable. The updated study titled "Antimicrobial Copper Alloys Group III Product Properties – Group A" Volume 2 of 2. MRID #482363-01 is acceptable.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

2/3/11

MEMORANDUM

SUBJECT: **Metallic Copper Alloys (P.C. Code 022501). Copper Alloy Products.** Evaluate human health concern associated with amended composition of inert metals in six registered groups of antimicrobial copper alloy touch products. DP Barcode/EPA Reg. No.: D382712/82012-1; D382755/82012-2; D382761/82012-3; D382765/82012-4; D382767/82012-5; and D382771/82012-6.

FROM: William J. Hazel, Ph.D., Chemist
and
Jonathan Chen, Ph.D., Toxicologist
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

THROUGH: A. Najm Shamim, Ph.D., Chemist
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)
and
Nader Elkassabany, Ph.D., Chief
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

TO: Karen Leavy-Munk, Team 33
Regulatory Management Branch I
Antimicrobials Division (7510P)

INTRODUCTION:

The Copper Development Association, Inc. (CDA), a group of copper producers, brass mills, wire and cable companies, foundries, etc., has proposed to amend the composition and upper limits of several intentionally-added inert metals in their six registered copper alloy products Antimicrobial Copper Alloys Groups I-VI (EPA Reg. Nos. 82012-1 to -6, respectively). These alloys are shaped into

objects that are frequently touched by human hands (touch surfaces) such as doorknobs, bed railings, IV poles, handles, knobs, etc. in health care facilities, community facilities, residential facilities, and limited playground equipment. Each alloy is comprised of a commercial copper source (the active ingredient) and at least one other element (an intentionally-added inert) depending on the object and disposition thereof. The actual active antimicrobial chemical species is the copper ion (largely Cu^{+2}) which would form gradually on the surface of the object constructed of the copper alloy depending on the environmental conditions. The inerts are generally metals that are added to impart certain properties to a given copper alloy such as strength, color, or corrosion resistance. The active ingredient (copper) and the inert ingredients were first determined not to be of human health concern in Groups I-V in an AD memorandum by W. Hazel and J. Chen dated 12/4/07 (D346663-D346668). Note that Antimicrobial Copper Alloys Group VI (EPA Reg. No. 82012-6) was not addressed in the 12/4/07 EPA memorandum.

CDA PROPOSAL:

The CDA has proposed several generally minor revisions to the upper limits for intentionally-added inert ingredients in Antimicrobial Copper Alloys Groups I-V. Membership in a specific Alloy Group is based on the percent by weight of copper in the alloy which has not been proposed to be changed. The number of alloys falling under each Alloy Group, however, has changed since each product was approved for registration. The subject 1/5/11 CSFs break out as follows:

Group I contains 186 alloys at a nominal concentration of 96.2% Cu
Group II contains 73 alloys at a nominal concentration of 91.3% Cu
Group III contains 60 alloys at a nominal concentration of 82.6% Cu
Group IV contains 36 alloys at a nominal concentration of 73.0% Cu
Group V contains 12 alloys at a nominal concentration of 66.5% Cu
Group VI contains 18 alloys at a nominal concentration of 62.0% Cu

In terms of inerts of potentially toxic concern, the 1/5/11 CSFs reflect removal of [redacted] from Group I. All other inerts of potentially toxic concern have remained the same as those considered in the 12/4/07 EPA review. A few changes in the upper limits for inerts having no expected toxic concern were also proposed; the only one of note (simply due to the magnitude of the change) was an increase in the upper limit f[redacted] in Group V by about [redacted]

CONCLUSIONS:

As presented in the 12/4/07 memorandum, the Agency has no human health toxicological concern over the major component of the five pending (and now six registered) Antimicrobial Copper Alloy Groups, i.e., the metallic copper. The

copper in the alloys is present in the metallic form which is essentially immobile and nontoxic in that form. The actual antimicrobial active ingredient is the copper ion which would form gradually and only on the surface of the object constructed of the copper alloy depending on the environmental conditions.

In terms of the many inert ingredients likely to be intentionally-added to make the various alloys, just as in the case of copper, each is present in the neutral, uncharged, or metallic form. Major ones may be [redacted]. The vast majority of the atoms of these elements will also remain in the neutral/metallic state and untouched by human hands. Only small amounts of cations (positively charged ions) of these neutral metals will form, and, again, these will form only on the surface. Regardless, the major intentionally-added inerts in the proposed products are not of human health concern to the Agency.

Regarding potentially toxic inert ingredients, the Agency has no concern for any ingredient in Groups III, IV, V, and VI. Based on the subject 1/5/11 CSFs, there are now only two inert metals that could potentially be of concern to the Agency. These inert ingredients of potential concern only apply to Groups I and II: [redacted]. As in the case of copper, virtually all atoms of these two metals are present in the neutral/metallic form and are present in the copper alloy product internally. Therefore, conversion to a more toxic cationic form would only occur to a very minimal extent on the alloy product surface. As discussed in the Agency's 12/4/07 memorandum, any additional exposure of humans to such low levels of these two metal ions from use of Antimicrobial Copper Alloy Groups I and II used to manufacture touch surfaces is expected to be negligible and is not considered to be of Agency concern.

Sign-off Date: 2/3/10
DP Barcodes: D382712, D382755, D382761, D382765, D382767, and D382771

Technology Sciences Group Inc.
1150 18th Street, Suite 1000
Washington, DC 20036
Direct: (202) 828-8967
Fax: (202) 872-0745
E-Mail: MReynolds@TSGUSA.com

Micah T. Reynolds
Regulatory Consultant

January 10, 2011

Copper Development Association Inc.
Resubmission of Amended Product Chemistry
Antimicrobial Copper Alloys Group III
EPA Reg. No. 82012-3

Mr. Marshall Swindell, PM-33
Ms. Karen Leavy
Antimicrobials Division (7504P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Document Processing Center
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202

Dear Mr. Swindell and Ms. Leavy:

Technology Sciences Group, Inc., on behalf of the Copper Development Association Inc., is submitting the enclosed amended supplemental product chemistry data volume for the above referenced product in response to reviewer comments received electronically on December 28-29, 2010. In that correspondence, the reviewer noted several inconsistencies between the submitted revised Confidential Statement of Formula and the corresponding data volume supporting revised Certified Limits. The enclosed amended study report addresses the reviewer's comments, corrects any inconsistencies and inaccuracies, and aligns with the revised Confidential Statement of Formula for this product.

It is important to note that this enclosed study report replaces the report previously submitted in September 2010 (MRID No. 48236301) for this amendment action; therefore, no PRIA fee is remitted for substitution of the current study with this amended/corrected version.

Please find enclosed the following documents supporting this amendment action:

1) EPA Application (EPA Form 8570-1);
2) Transmittal Document;
3) Amended Supplemental Product Chemistry (Certified Limits; EPA/OPPTS 830.1750) (3 copies).

If you have any questions or require additional information or clarification, please do not hesitate to contact me by phone at (202) 828-8967 or by e-mail at mreynolds@tsgusa.com.

Sincerely,

Regulatory Consultant to the
Copper Development Association Inc.

Enclosures

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter (Registrant)

EPA Company No. 82012

Copper Development Association
260 Madison Avenue
New York, NY 10016

Authorized Representative:

Micah T. Reynolds
Technology Sciences Group, Inc.
1150 18th Street, NW, Suite 1000
Washington, DC 20036
Tel: (202) 828-8967

2. Regulatory Action for which this Package is Submitted:

Resubmission of supplemental product chemistry data to support addition of copper alloys to Antimicrobial Copper Alloys Group III (EPA Reg. No. **82012-3**)

3. Transmittal Date

January 10, 2011

4. List of Submitted Documents

Volume 1 Administrative Materials:
- Cover Letter;
- Application for Registration (EPA Form 8570-1);
- Transmittal Document.

Volume 2 Antimicrobial Copper Alloys Group III;
Supplemental Product Chemistry (EPA/OPPTS 830.1750)

5. Company Contact

Company Name: Copper Development Association Inc.

Authorized Representative:

Micah T. Reynolds
Regulatory Consultant
Technology Sciences Group, Inc.
Email: mreynolds@tsgusa.com

Telephone: (202) 828-8967
FAX: (202) 872-0745

Please read instructions on reverse side before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA	United States Environmental Protection Agency Washington, DC 20460	☐ Registration ☒ Amendment ☐ Other	OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
82012-3	**Marshall Swindell**	☒ None ☐ Restricted
4. Company/Product (Name) **Antimicrobial Copper Alloys Group III**	PM# **33**	

5. Name And Address Of Applicant *(Include ZIP Code)*

Copper Development Association Inc.
260 Madison Avenue
New York, NY 10016

☐ *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section II

☐ Amendment – Explain below.
☒ Resubmission in response to Agency letter dated 12/28/2010
☐ Notification – Explain below.
☐ Final Printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other – Explain Below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Resubmission of amended product chemistry data volume (Certified Limits; EPA/OPPTS 830.1750) in response to reviewer comments in electronic correspondence dated December 28-29, 2010.
Please confirm receipt with Micah Reynolds: mreynolds@tsgusa.com, via phone (202) 828-8967, or via fax (202) 872-0745.

Section III

1. Material This Product Will Be Packaged In:

Child Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No	☐ Yes ☒ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☒ Other (Specify) none
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Unit Packaging wgt. / No. per Container	

3. Location of Net Contents Information	4. Size(S) Retail Container	5. Location of Label Directions
☒ Label ☐ Container	**N/A – no container**	☒ On Label ☒ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithographed ☐ Pager glued ☐ Stenciled ☒ Other Attached to Bill of Lading

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Micah T. Reynolds, Technology Sciences Group, Inc.	**Regulatory Consultant**	**(202) 828-8967**

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature	3. Title	5. Date
Micah T. Reynolds	**Regulatory Consultant to Copper Development Association Inc.**	**January 10, 2011**
4. Typed Name **Micah T. Reynolds**		

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 11, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JOSEPH J. GREEN
COLLIER SHANNON SCOTT, PLLC
COPPER DEVELOPMENT ASSOCIATION (CDA)
3050 K STREET, N.W., SUITE 400
WASHINGTON, DC 20007-

PRODUCT NAME: ANTIMICROBIAL COPPER ALLOYS - GROUP III
COMPANY NAME: COPPER DEVELOPMENT ASSOCIATION (CDA)
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 82012-3
EPA RECEIPT DATE: 01/10/11

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 33, at (703) 308-6341.

Sincerely,

P. K. Moore
Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service

{888610!~

This package includes the following

- ○ New Registration
- ◉ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ◉ AD
- ○ BPPD
- ○ RD

Risk Mgr. 33

Receipt No. S- 888610

EPA File Symbol/Reg. No. 82012-3

Pin-Punch Date: 1/10/2011

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: $ _____

Parent/Child Decisions:

▣ Inert Cleared for Intended Use ▣ Uncleared Inert in Product

Reviewer: Team 1 Date: 1/11/11

Remarks:

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.
Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Copper Development Association, 260 Madison Ave., NY, NY 10016-2401 Tel.: 212-251-7234	EPA Registration Number/File Symbol 82012-3
Active Ingredient(s) and/or representative test compound(s) Copper (metallic)	Date September 20, 2010
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor, non-food	Product Name Antimicrobial Copper Alloys Group III

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☑ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Heather R Bjornson	9/20/2010	Heather Bjornson, Regulatory Consultant

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date September 20, 2010	EPA Reg No./File Symbol **82012-3**	Page 1 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group 3	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	46999301 47259201	Copper Development Association	Own	
830.1600	Description of Materials Used to Produce Product	46999301	Copper Development Association	Own	
830.1620	Description of Production Process	46999301	Copper Development Association	Own	
830.1650	Description of Formulation Process	46999301	Copper Development Association	Own	
830.1670	Discussion of Formation of Impurities	46999301	Copper Development Association	Own	
830.1700	Preliminary Analysis	46999301 47160802	Copper Development Association	Own	
830.1750	Certified Limits	46999301 This submission	Copper Development Association	Own	
830.1800	Enforcement Analytical Method	46999301	Copper Development Association	Own	
830.1900	Submittal of Standards	46999301	Copper Development Association	Own	

Signature	Name and Title	Date
Heather R. Bjornson	Heather Bjornson, Regulatory Agent	9/20/2010

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date September 20, 2010	EPA Reg No./File Symbol **82012-3**	Page 2 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group 3	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6302	Color				Not required OPPTS 830.1000
830.6303	Physical State	47160801	Copper Development Association	Own	
830.6304	Odor				Not required OPPTS 830.1000
830.6313	Stability to Temperature, Metals, and Metal Ions				Not required OPPTS 830.1000
830.6314	Oxidation/Reduction	47160801	Copper Development Association	Own	
830.6315	Flammability	47160801	Copper Development Association	Own	
830.6316	Explodability	47160801	Copper Development Association	Own	
830.6317	Storage Stability	47160801	Copper Development Association	Own	
830.6319	Miscibility	47160801	Copper Development Association	Own	
830.6320	Corrosion Characteristics	47160801	Copper Development Association	Own	
830.6321	Dielectric Breakdown Voltage	47160801	Copper Development Association	Own	
830.7000	pH	47160801	Copper Development Association	Own	
830.7050	UV/Visible Absorption				Not required OPPTS 830.1000
830.7100	Viscosity	47160801	Copper Development Association	Own	

Signature	Name and Title	Date
Heather R Bjornson	Heather Bjornson, Regulatory Agent	9/20/2010

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date September 20, 2010	EPA Reg No./File Symbol **82012-3**	Page 3 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group 3	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7200	Melting Point/Melting Range				Not required OPPTS 830.1000
830.7220	Boiling Point/Boiling Range				Not required OPPTS 830.1000
830.7300	Density/Relative Density/Bulk Density	47160801	Copper Development Association	Own	
830.7370	Dissociation Constants in Water				Not required OPPTS 830.1000
830.7550	Partition Coefficient (n-octanol/water)				Not required OPPTS 830.1000
830.7840	Water Solubility				Not required OPPTS 830.1000
830.7950	Vapor Pressure				Not required OPPTS 830.1000

Signature	Name and Title	Date
Heather R. Bjornson	Heather Bjornson, Regulatory Agent	9/20/2010

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date September 20, 2010	EPA Reg No./File Symbol **82012-3**	Page 4 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group 3	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute Oral Toxicity - Rats	46999302	Copper Development Association	Own	
870.1100	Acute Oral Toxicity - Mice	46999302	Copper Development Association	Own	
870.1200	Acute Dermal Toxicity	46999302	Copper Development Association	Own	
870.1300	Acute Inhalation Toxicity	46999302	Copper Development Association	Own	
870.2400	Acute Eye Irritation	46999302	Copper Development Association	Own	
870.2500	Acute Dermal Irritation	46999302	Copper Development Association	Own	
870.2600	Skin Sensitization	46999302	Copper Development Association	Own	
870.3150	90-Day Oral Toxicity - Dogs	46999302	Copper Development Association	Own	
870.3465	90-Day Oral Toxicity - Rats	46999302	Copper Development Association	Own	
870.3700	Prenatal Developmental Toxicity - Rabbits	46999302	Copper Development Association	Own	
870.3700	Prenatal Developmental Toxicity - Rats	46999302	Copper Development Association	Own	
870.3800	Reproduction and Fertility Effects - 2 Gen	46999302	Copper Development Association	Own	
870.4100	Chronic Feeding, Dog	46999302	Copper Development Association	Own	
870.4100	Chronic Feeding, Rat	46999302	Copper Development Association	Own	
870.5100	Bacterial Reverse Mutation (Ames) Test	46999302	Copper Development Association	Own	
870.	Other Mutagenicity	46999302	Copper Development Association	Own	
870.7485	Metabolism and Pharmacokinetics - Rat	46999302	Copper Development Association	Own	

Signature	Name and Title	Date
Heather R Bjornson	Heather Bjornson, Regulatory Agent	9/20/2010

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date September 20, 2010	EPA Reg No./File Symbol **82012-3**	Page 5 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group 3	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.2000	Hard Surface Sanitizer Assay S. aureus (ATCC 6538), E. aerogenes (ATCC) 13048)	46999306	Copper Development Association	OWN	
810.2000	Hard Surface Sanitizer Assay MRS. aureus (ATCC 33592), E. coli (ATCC 35150), P. aeruginosa (ATCC 15442)	46999307	Copper Development Association	OWN	
810.2000	Hard Surface Sanitizer Assay S. aureus (ATCC 6538), E. aerogenes (ATCC) 13048)	46999310	Copper Development Association	OWN	
810.2000	Hard Surface Sanitizer Assay S. aureus (ATCC 6538), E. aerogenes (ATCC) 13048)	46999312	Copper Development Association	OWN	
810.2000	Hard Surface Sanitizer Assay VRE. faecalis (ATCC 51575)	47859501	Copper Development Association	OWN	
810.2000	Residual Self-sanitizer Assay S. aureus (ATCC 6538), E. aerogenes (ATCC)	46999308	Copper Development Association	OWN	
810.2000	Residual Self-sanitizer Assay MRS. aureus (ATCC 33592), E. coli (ATCC 35150), P. aeruginosa (ATCC 15442)	46999309	Copper Development Association	OWN	
810.2000	Residual Self-sanitizer Assay VRE. faecalis (ATCC 51575)	47859502	Copper Development Association	OWN	
810.2000	Repeat Challenge Assay S. aureus (ATCC 6538), E. aerogenes (ATCC 13048)	46999304	Copper Development Association	OWN	
810.2000	Repeat Challenge Assay MRS. aureus (ATCC 33592), E. coli (ATCC 35150), P. aeruginosa (ATCC 15442)	76999305	Copper Development Association	OWN	
810.2000	Repeat Challenge Assay S. aureus (ATCC 6538), E. aerogenes (ATCC 13048)	4699311	Copper Development Association	OWN	
810.2000	Repeat Challenge Assay S. aureus (ATCC 6538), E. aerogenes (ATCC 13048)	46999312	Copper Development Association	OWN	
810.2000	Repeat Challenge Assay VRE. faecalis (ATCC 51575)	47859503	Copper Development Association	OWN	

Signature	Name and Title	Date
Heather R Bjorn	Heather Bjornson, Regulatory Agent	9/20/2010

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date September 20, 2010	EPA Reg No./File Symbol **82012-3**	Page 1 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group 3	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	

Signature	Name and Title	Date
Heather R Bjornson	Heather Bjornson, Regulatory Agent	9/20/2010

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date September 20, 2010	EPA Reg No./File Symbol **82012-3**	Page 2 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group 3	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Not required OPPTS 830.1000
			Copper Development Association	Own	
					Not required OPPTS 830.1000
					Not required OPPTS 830.1000
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
					Not required OPPTS 830.1000
			Copper Development Association	Own	

Signature	Name and Title	Date
Heather R. Bjornson	Heather Bjornson, Regulatory Agent	9/20/2010

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date September 20, 2010	EPA Reg No./File Symbol **82012-3**	Page 3 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group 3	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Not required OPPTS 830.1000
					Not required OPPTS 830.1000
			Copper Development Association	Own	
					Not required OPPTS 830.1000
					Not required OPPTS 830.1000
					Not required OPPTS 830.1000
					Not required OPPTS 830.1000

Signature	Name and Title	Date
Heather R Bjornson	Heather Bjornson, Regulatory Agent	9/20/2010

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date September 20, 2010	EPA Reg No./File Symbol **82012-3**	Page 4 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group 3	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	

Signature	Name and Title	Date
Heather R Bjornson	Heather Bjornson, Regulatory Agent	9/20/2010

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date September 20, 2010	EPA Reg No./File Symbol **82012-3**	Page 5 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group 3	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	

Signature	Name and Title	Date
Heather R. Bjornson	Heather Bjornson, Regulatory Agent	9/20/2010

KELLER AND HECKMAN LLP
Serving Business through Law and Science®

1001 G Street, N.W.
Suite 500 West
Washington, D.C. 20001
tel. 202.434.4100
fax 202.434.4646

481261-00

Writer's Direct Access
John B. Dubeck
(202) 434-4125
dubeck@khlaw.com

June 16, 2010

Via Courier

Document Processing Desk (AMEND)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

To: Marshall Swindell (7510P)
PM Team 33
Regulatory Management Division Branch I

Re: Registrant: FMC Corporation, Peroxygens Division
Product: VigorOx® SP-15 Antimicrobial Agent (EPA Reg. No. 65402-3)
Label Amendment to Add Pathogenic Claims
PRIA Code: A570 (Label amendment requiring data submission)
PRIA Fee: $3308; Review Time: 4 months

Dear Marshall:

On behalf of our client, FMC Corporation, Peroxygens Division, we are submitting a label amendment for VigorOx® SP-15 Antimicrobial Agent (EPA Reg. No. 65402-3). The current label includes the following use: "For treatment of processing water to control growth of non-public health microorganisms that can cause spoilage of fresh-cut, post-harvest or processed fruits and vegetables." This label amendment expands this claim to include public health organisms. The new claim is "Reduces (in 90 seconds) 99.9% of pathogenic foodborne bacteria in processing water for fruits and vegetables." The three pathogens covered by this label amendment are:

- *Escherichia coli*,
- *Salmonella enterica*, and
- *Listeria monocytogenes*.

Attached are three copies of the efficacy study that supports this new claim.

No other changes to the labeling have been made. Attached are 5 copies of the proposed label along with a highlighted version of the proposed changes.

KELLER AND HECKMAN LLP

* * *

If you have questions or need additional information, please contact either Cathy Rice at 202-434-4145 or me at the number listed above so that we can respond immediately

Sincerely,

John B. Dubeck
Regulatory Counsel

cc: LuAnn Maloney, FMC Corporation

48126101 Efficacy of Antimicrobial Agents in Reducing Pathogenic Foodborne Bacteria in Processing Waters for Fruits and Vegetables

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 9-22-10

Experts In-Processing Signature: MF HARRINGTON Date 9-24-10 Fee Paid: Yes ✓

Division management contacted on issues No_____ Yes_____ Date_____

EPA Reg. Number: 82012-3	EPA Receipt Date: 9-22-10

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	**yes** X	**no**			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	**yes**	**no**			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	**Data Matrix** (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	**yes** X	**no**			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to** http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels **)**				X	

7	**Is the data package consistent with PR Notice 86-5** (link to PRN 86-5)	X		
8	**Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)**			X
9	**If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)**			X
10	**Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

Inerts approved for non food use only
Passed 86-5 Review without any contact
to registrant MRID 482363

JD 9/27/10

MRID 482363

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 23, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-440114
EPA File Symbol or Registration Number: 82012-3
Product Name: ANTIMICROBIAL COPPER ALLOYS - GROUP III
EPA Receipt Date: 22-Sep-2010
EPA Company Number: 82012
Company Name: COPPER DEVELOPMENT ASSOCIATION (CDA)

JOSEPH J. GREEN
COLLIER SHANNON SCOTT, PLLC
COPPER DEVELOPMENT ASSOCIATION (CDA)
3050 K STREET, N.W., SUITE 400
WASHINGTON, DC 20007-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A570

AMENDMENT;NON-FAST TRACK;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6427.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{8826446~

This package includes the following

- ○ New Registration
- ◉ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ◉ AD
- ○ BPPD
- ○ RD

33

Risk Mgr. 3

Receipt No. S-	882644
EPA File Symbol/Reg. No.	82012-3
Pin-Punch Date:	9/22/2010

☐ This item is NOT subject to FFS action.

Action Code:

Requested:	A570
Granted:	A570
Amount Due: $	0.00

Parent/Child Decisions:

▣ Inert Cleared for Intended Use ▣ Uncleared Inert in Product

Reviewer: Team 3 Date: 09/23/2010

Remarks: Paid $3,308.00

To Veronica
From Marshall
This is the correct bean sheet for this data
Thanx

DATA PACKAGE BEAN SHEET

Date: 05-Oct-2010

Decision #: 440114
DP #: (382757)
PRIA
Parent DP #:
Submission #: 882644

KL

* * * Registration Information * * *

Registration: 82012-3 - ANTIMICROBIAL COPPER ALLOYS - GROUP III
Company: 82012 - COPPER DEVELOPMENT ASSOCIATION (CDA)
Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828
Risk Manager Reviewer: Karen Leavy KLEAVY
Sent Date: _____ Calculated Due Date: 13-Feb-2011 Edited Due Date: _____
Type of Registration: Product Registration - Section 3
Action Desc: (A570) AMENDMENT;NON-FAST TRACK;
Ingredients: 022501, Copper as elemental(82.6%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 05-Oct-2010 Due Back: _____
DP Ingredient: 022501, Copper as elemental
DP Title: _____
CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #: _____

120
90

Assigned To	Date In	Date Out	
Organization: AD / PSB	10/13/10		Last Possible Science Due Date: 14-Jan-2011
Team Name: CTT	10/13/10	11/1/11	Science Due Date: 12/28/10
Reviewer Name: Jno	10/14/10	11/1/11	Sub Data Package Due Date: 1/14/11
Contractor Name:			

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

Please review the product chemistry data submitted in support of the the amendment to add additional alloys to the product registration.
PRIA, Action Code A570, Admin. Due Date 02/13/11, CTT Due Date 01/13/11

RECEIVED 10/13/10

VOLUME 1 OF 2 OF SUBMISSION

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Copper Development Association Inc.
260 Madison Avenue
New York, NY 10016

REGULATORY ACTION:

Submission of product chemistry data to support the addition of additional copper alloys to Antimicrobial Copper Alloys Group III, EPA Reg. No. 82012-3.

TRANSMITTAL DATE:

September 20, 2010

LIST OF SUBMITTED STUDIES:

MRID NUMBER	VOLUME NUMBER	EPA STUDY TITLE	GUIDELINE NUMBER
	1 of 2	(Transmittal Document)	----------
48236301	2 of 2	Antimicrobial Copper Alloys Group III Supplemental Product Chemistry	830.1750

COMPANY NAME: Copper Development Association Inc.

COMPANY OFFICIAL: Heather R. Bjornson, Regulatory Consultant

COMPANY CONTACT:

Heather R. Bjornson, Regulatory Consultant
Technology Sciences Group, Inc.
1150 18th Street, N.W. Ste.1000
Washington, DC 20036
(202) 828-8963

Material to be added to an e-Jacket/Jack

Reg. No. 8201213

1. ☑ **Placement within the e-Jacket/jacket:**
   - ☐ **Default: (chronological, top/newest)**
   - ☐ **Description: (PDF page number, i.e., "before pag 45")**

_____

_____

2. ☐ **Send to Data Extraction contractors this material:**
   - ☐ **Newly stamped accepted label**
   - ☐ **Notification**
   - ☐ **New CSF**
   - ☑ **Other:** Amendment

3. Attach this coversheet to the top of the material or jacket. must be well organized and clipped together, NOT STAPLEI Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: K Leavy

Phone: _____ **Division:** AD

Date: 11/16/12

Created July 21,

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

NOV 10 2010

Mr. Joseph J. Green
Counsel to the Copper Development Association
Copper Development Association
260 Madison Avenue
New York, New York 10016-2401

Subject: Antimicrobial Copper Alloys Group III
EPA Registration Number 82012-3
Your Amendment Dated November 10, 2010
EPA Received Date November 10, 2010

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to revise the master label which also includes a fabricated product label is acceptable subject to the comments listed below:

1) The fabricator cannot make claims about the basic copper alloy product or ingredient or fabricated article (doorknob, handrail, etc.) that conflict with statements required pursuant to FIFRA on either the basic copper alloy product or any fabricated product label. For example, the accepted master label for the basic copper alloy as well as the label for the fabricated product that is included within the master label state "Normal tarnishing or wear of the surface will not impair antibacterial effectiveness." Additionally, in support of your application for registration of the basic copper alloy products, you submitted data supporting your position that tarnish has a beneficial impact on product efficacy against target microorganisms. Hence, the warranty statement, for example, on either the basic copper alloy product or any fabricated product cannot make a non-tarnish claim as that would conflict with the above required label statement.

2) The EPA Establishment Number that appears on the labeling for the alloy product labeling and/or the labeling for the fabricated end-use article to being sold or distributed must be that of the establishment where the particular product it is being produced and labeled. For the alloy product, it would be the establishment where the alloy product is produced and labeled. For the fabricated end-use article, it would be the establishment where the fabricated end-use article is produced and labeled. It is the responsibility of the owner of the establishment where the final production takes place to report production, and to maintain books and records under under FIFRA Sections 7 and 8 and 40 CFR 167 and 169.

3) The labels attached to the copper alloy and the end-use fabricated products must contain the name and address of the producer, registrant, or person for whom produced in accordance with 40 CFR 156.10(c).

A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)308-6237.

Sincerely,

Dennis H Edwards Jr for

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510C)

ANTIMICROBIAL COPPER ALLOYS GROUP III AND ASSOCIATED FABRICATED PRODUCTS MASTER LABEL

The Master Label consists of the label that will accompany the Antimicrobial Alloys and a label that will accompany each product fabricated using a registered alloy from Antimicrobial Copper Alloys Group III.

[Alloy Label – Front Panel]

ANTIMICROBIAL COPPER ALLOYS GROUP III AND ASSOCIATED FABRICATED PRODUCTS

Active Ingredient:	
Copper	82.6%
Other	17.4%
Total	100%

EPA Registration No. 82012-3
EPA Establishment No. *****

Made in the United States by *******
Distributed by *******

Net Weight: XXX lbs XXX ounces of [brand name]

ACCEPTED
with COMMENTS
EPA Letter Dated:
NOV 10 2010
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 82012-3

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Antimicrobial Copper Alloys Group III

These alloys are only intended for the manufacture and fabrication of touch surface components for use in hospitals, healthcare facilities, and various public, commercial, and residential buildings. [The claims listed on the attached fabricated product label may be made in connection with the marketing and sale of Antimicrobial Copper Alloys Group III and fabricated products made from Antimicrobial Copper Alloys Group III under EPA Registration Number 82012-3.]

A list of components that may be fabricated out of Antimicrobial Copper Alloys Group III is specified below. Antimicrobial Copper Alloys Group III are not approved for direct food contact or food packaging uses.

Touch Surface Components

Healthcare Facilities

- Bedrails, footboards
- Over-bed tables
- Bed-side tables in hospitals, extended care facilities, senior housing etc. (knobs, pulls, handles; surfaces)
- Handrails, (corridor/hallways) (Senior housing), automatic door push plates
- Stair rails, handrails, tubular railing, and supports, rail fittings T's, elbows and brackets
- Bedrails, assistance rails,
- Toilet safety rails
- Carts
  - Hospital carts (table surfaces, handles, legs)
  - Computer carts
  - Record carts
  - Phlebotomy carts
  - Other Carts (tables/surfaces, shelving, railings, handles, pulls)
- Equipment carts (horizontal surfaces, frames, handles)
- Door push plates, kick plates, mop plates, stretcher plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Water fountains: bubbler head, drain strainer, handle
- Alcohol sanitizer dispenser, handle
- Paper towel holders, facial tissue holders, toilet paper holders
- Air hand dryer, controls and push buttons on air hand dryers
- Hydrotherapy tanks (whirlpool tanks): shells, covers, headrests, drain fittings (outer surfaces without water contact)
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Panic bars on emergency room doors
- Towel bars

ACCEPTED
with COMMENTS
EPA Letter Dated:
NOV 10 2010
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 82012-3

- Showerheads
- Countertops and tabletops (non-food use only)
- Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Closures
- Vertical locking arms
- Vertical cover guards
- Protection bars
- Light switches, switch plates
- Visitor chairs: armrests, metal frames
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Floor tiles
- Ceiling tiles (non-porous)
- Wall tiles
- Instrument handles

  Medical equipment knobs, pulls and handles for:
  - Drug delivery systems
  - Monitoring systems
  - Hospital beds
  - Office equipment
  - Operating room equipment
  - Stands and fixtures

  Types of knobs: *e.g.*, Prong, fluted, knurled, push/pull, T-handle, tapered, and ball knobs
- Intravenous (IV) poles, bases, hangers, clips
- Trays (instruments, non-food contact)
- Pans (bed)
- Walkers, wheelchair handles, and tubular components
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise and rehabilitation equipment, handles, bars
- Physical therapy equipment: physical therapy tables, treatment chairs and portable taping tables
- Chairs (shower chairs, patient chairs, visitor chairs): rails, backs, legs, seats
- Lighting products: X-ray illuminators, operating rooms, patient examination rooms, surgical suites, and reading lamps for hospital rooms and assisted living facilities etc. Components can include bases, arms, housings, handles, hinges)
- Headwall systems: the unit themselves, outlet covers, knobs and dials, lighting units (lamp housings and adjustable arms), CRT monitors with rotating knobs and levers and adjustments. Baskets, monitor housings, knobs, baskets, tables, IV poles

ACCEPTED
with COMMENTS
EPA Letter Dated:
NOV 10 2010
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 82012-3

- Critical care cart: Table top, drawer, drawer pull, lock, copper wire baskets for storage of equipment and charts.
- Bedside lavatory: sink, faucet, handles, drawer pulls, toilet seat, toilet seat cover, toilet handle, door and cabinet facings, counter tops
- Medical records: Chart holders, clipboards, filing systems
- Storage Shelving: wire shelving etc. for medical supplies
- Grab handles on privacy curtains
- Lids of laundry hampers, trash canisters, and other containers
- Bedside pitchers
- Closet rods and hangers
- Television controls: knobs, buttons, remote
- Monitor (television, computer, etc.) housing
- Cup Holder
- Toothbrush holder
- Soap holder
- Magazine rack
- Signage
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Bracelets
- Pens
- Badge clips
- Name tags
- Patient gown snaps
- Window sills, pulls and locks
- Electrical wallplates

ACCEPTED
with COMMENTS
EPA Letter Dated:

NOV 10 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 82012-3

Community Facilities (including various public and commercial buildings)

- Shopping cart handles, child seats, handrails
- Cash registers: housing, keypads
- ATM machines: keys, housing
- Gym/Health club lockers, locker handles, locker shelving, trainers' tables,
- Ice and water dispensers (outer surfaces without water contact)
- Elevator: handrail, control panel, buttons, interior walls, floor tiles, exterior call button plate
- Paper towel dispensers. Housing itself, (turn) handle, (push) handle
- Soap holder
- Soap dispenser (wall mounted): push bar and dispenser itself
- Soap dispenser (sitting on counter): dispenser housing itself, push mechanism
- Toilet paper dispenser (housing)
- Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)
- Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)
- Light switches, switch plates

- Lids of laundry hampers, trash canisters, and other containers
- Magazine rack
- Signage
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Bracelets
- Badge clips
- Name tags
- Vending machines (non-food contact only)
- Window sills
- Electrical wallplates
- Clip boards
- Office supplies: paper clips, staplers, tape dispensers

Residential Buildings (including homes, apartments, apartment buildings and other residences)

- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Bedrails, footboards
- Handrails
- Stair rails
- Door push plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Paper towel holders, facial tissue holders, toilet paper holders
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Towel bars
- Showerheads
- Countertops and tabletops
- Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Light switches, switch plates
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- Floor tiles
- Ceiling tiles (non-porous)
- Wall tiles
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise equipment, handles, bars
- Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)

ACCEPTED
with COMMENTS
EPA Letter Dated:

NOV 10 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 82012-3

- Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)
- Television control knobs and buttons
- Lids of laundry hampers, trash canisters, and other containers
- Bedside pitchers
- Closet rods and hangers
- Television remote
- Cup Holder
- Toothbrush holder
- Soap holder
- Magazine rack
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Window sills
- Electrical wallplates
- Baby cribs: rails, fittings, brackets, supports
- Bowl stands
- Office supplies: paper clips, staplers, tape dispensers
- Monitor (television, computer, etc.) housing

Mass Transit Facilities

- Handrails
- Stair rails, tubular railing, and supports; elbows and brackets
- Door push plates, kick plates
- Door handles, door knobs (outer touch surfaces)
- Grab bars and handles
- Tiles: wall, floor, ceiling (non-porous)
- Chairs and benches: rails, backs, legs, seats
- Window sills, pulls, and handles
- Signage
- Vending machines (non-food contact only)

Other

- Play area equipment (indoor only): bars, handles, chains, push plates, handrails, stair rails and risers, wheels, knobs, flooring
- Chapel pews
- Eye glass frames and protective eye wear
- Pens
- Combs
- Ashtrays

Do not wax, paint, lacquer, varnish, or otherwise coat touch surfaces.

Antimicrobial Copper Alloys Group III – Fabricated Products

The Antimicrobial Copper Alloys Group III fabricated products listed above may be sold and distributed under EPA Registration Number 82012-3. Products fabricated with Antimicrobial Copper Alloys Group III must bear the EPA approved fabricated product label, below, with one or more of the listed claims.

STORAGE AND DISPOSAL

Dispose of excess by recycling.

WARRANTY STATEMENT

If used as intended, this product is wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.

ACCEPTED
with COMMENTS
EPA Letter Dated:

NOV 10 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 82012-3

ANTIMICROBIAL COPPER ALLOYS GROUP III

Fabricated Product Label

FRONT

[This (touch surface) (product)] made from

Antimicrobial Copper Alloys Group III

Active Ingredient:
Copper 82.6%
Other..... ... 17.4%
[Total 100.0%]
See [Back/Side Panel][Insert] for Directions for Use
Net Weight: XXX lbs XXX ounces of [brand name]

ACCEPTED
with COMMENTS
EPA Letter Dated:

NOV 10 2010

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 82012-3

BACK

ANTIMICROBIAL COPPER ALLOYS GROUP III

Laboratory testing has shown that when cleaned regularly this surface:

- Continuously reduces bacteria* contamination, achieving 99.9% reduction within 2 hours of exposure.
- Kills greater than 99.9% of Gram-negative and Gram-positive bacteria* within 2 hours of exposure.
- Delivers continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within 2 hours.
- Kills greater than 99.9% of bacteria* within two hours and continues to kill 99% of bacteria* even after repeated contaminations.
- Helps inhibit the buildup and growth of bacteria* within 2 hours of exposure between routine cleaning and sanitizing steps.
- [This product/component name] is made (out of)(from) a (copper)(touch) surface that continuously kills bacteria left behind [by dirty hands][on the surface] killing more than 99.9% of bacteria within 2 hours.

* *Staphylococcus aureus*, *Enterobacter aerogenes*, Methicillin-Resistant *Staphylococcus aureus* (MRSA), *Escherichia coli* O157:H7, *Pseudomonas aeruginosa* and, Vancomycin – Resistant *Enterococcus faecalis (VRE).*

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Proper Care and Use. Clean and sanitize according to standard practice. Healthcare facilities must maintain the product in accordance with infection control guidelines. The use of this surface is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces. This surface has been shown to reduce microbial contamination, but does not necessarily prevent cross contamination.

This surface may be subject to recontamination and the level of active bacteria at any time will depend on the frequency and timing of recontamination and cleanliness of the surface (among other factors). In order to have proper antimicrobial effect, this product must be cleaned and maintained according to the directions for use.

Do not wax, paint, lacquer, varnish, or otherwise coat this product.

Routine cleaning to remove dirt and filth is necessary for good sanitation and to assure the effective antibacterial performance of this surface. Cleaning agents typically used for traditional hard, non-porous touch surfaces are permissible. The appropriate cleaning agent depends on the type of soiling and the measure of sanitization required. Normal tarnishing or wear of this surface will not impair antibacterial effectiveness.

Not approved for direct food contact or food packaging uses.

[Items exposed to outdoor environmental conditions are not representative of indoor laboratory test conditions, and, therefore, may impart reduced efficacy if not cleaned when visibly soiled.]

STORAGE AND DISPOSAL

Dispose of by recycling or put in trash.

WARRANTY STATEMENT

If used as intended, this product is wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.

EPA Reg. No. 82012-3 EPA Est. No. [Product Manufacturer Number] 82012-NY-001
Manufactured by: [Product Manufacturer Company Name and Address]
Copper Development Association, 260 Madison Ave., NY, NY 10016-240

KELLEY DRYE & WARREN LLP
A LIMITED LIABILITY PARTNERSHIP

WASHINGTON HARBOUR, SUITE 400
3050 K STREET, NW
WASHINGTON, D.C. 20007-5108

(202) 342-8400

NEW YORK, NY
CHICAGO, IL
STAMFORD, CT
PARSIPPANY, NJ

BRUSSELS, BELGIUM

AFFILIATE OFFICES
MUMBAI, INDIA

FACSIMILE
(202) 342-8451
www.kelleydrye.com

JOSEPH J. GREEN
DIRECT LINE: (202) 342-8849
EMAIL: jgreen@kelleydrye.com

November 10, 2010

Dennis J. Edwards, Branch Chief (7510C)
Regulatory Management Branch I
Antimicrobial Division, Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C.

Re: Antimicrobial Copper Alloys Groups III, EPA Reg. Nos. 82012-3 Submission of Label Amendments

Dear EPA and Branch Chief Edwards:

On behalf of the Copper Development Association (CDA), we are submitting the attached amendments to the registrations for Antimicrobial Copper Alloys Groups I-VI. These amendments reflect the labeling that CDA and EPA negotiated over the last year to enable the marketing of Antimicrobial Copper Alloys and products fabricated from these alloys. EPA's acceptance of these amendments for Antimicrobial Copper Alloys Group II (EPA Reg. No. 82012-2) is detailed in the attached letter from Marshall Swindell dated November 10, 2010. The amended labels for the other five alloy groups are identical to the Group II label, with the exception of product name and registration number.

The amended labeling allows for the marketing, sale and distribution of Antimicrobial Copper Alloys throughout the supply chain, from alloy manufacturers to distributors to retailers of consumer and commercial products. The Master Label identifies components that may be manufactured out of Antimicrobial Copper Alloys Groups I-VI. Products fabricated with Antimicrobial Copper Alloys Group I-VI must bear the EPA approved fabricated product label, which also is included as part of the Master Label. The fabricated product label indicates that the product is made from an Antimicrobial Copper Alloy and identifies claims that may be made for the Antimicrobial Copper Alloy used in the manufacture of the product. The fabricated product label will bear the EPA registration number of the alloy manufacturer, and an appropriate establishment number for the facility that produces the final product that is placed on the market. Products that bear the fabricated product label do not require additional registration or labeling at the federal or state level.

As a condition of the EPA registration, CDA and CDA members that manufacture Antimicrobial Copper Alloys are required to promote product stewardship and compliance with the labeling and marketing requirements established by EPA. This includes alloy manufacturer education of customers that purchase and utilize Antimicrobial Copper Alloys to manufacture final products. CDA is committed to fulfilling these stewardship obligations.

Enclosed in the application package are the following items:

(1) This cover letter describing the applications;

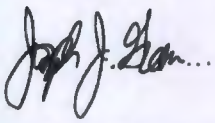
(2) Letter from EPA dated November 10, 2010, detailing the agency's acceptance of the revised labeling for Antimicrobial Copper Alloys Group II (EPA Reg. No. 82012-2);

(3) The fast track amendment application form; and

(4) Five copies of the revised labeling.

As we have discussed, we look forward to receiving prompt EPA approval of the attached labels for all of the alloy groups. I will send electronic versions of the CDA and "me too" member company fast-track label amendment applications directly to Karen Leavy to help expedite the process. Please let me know if you have any questions.

Best regards,



Joseph J. Green
Counsel to the Copper Development Association

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☑ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
82012-3	Marshall Swindell	☑ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
Antimicrobial Copper Alloys Group III	33	

5. Name and Address of Applicant *(Include ZIP Code)*

Copper Development Association Inc.
260 Madison Avenue
New York, NY 10016

☐ *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☑ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This is a fast-track label amendment and is not subject to PRIA. Agency requested label changes.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☑ No	☐ Yes ☑ No	☐ Yes ☑ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☑ Other (Specify) none
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☑ Label ☐ Container	NA- no container	☑

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☑ Other Attached to Bill of Lading

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Robert Stewart, Technology Sciences Group, Inc.	Regulatory Consultant	(202) 828-8963

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Robert R Stewart	Regulatory Consultant to Copper Development Assoc. Inc.
4. Typed Name	**5. Date**
Robert Stewart	November 10, 2010

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Material to be added to an e-Jacket/Jacke

Reg. No. 82018-3

1. ☑ Placement within the e-Jacket/jacket:
   - ☐ Default: (chronological, top/newest)
   - ☐ Description: (PDF page number, i.e., "before page 45")

2. ☐ Send to Data Extraction contractors this material:
   - ☐ Newly stamped accepted label
   - ☐ Notification
   - ☐ New CSF
   - ☑ Other: Amendment

3. Attach this coversheet to the top of the material or jacket. I must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: K Leavy

Phone: 308-6237 Division: AD

Date: 2/9/11

Created July 21/2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

FEB 9 2010

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ms. Heather R. Bjornson
Regulatory Assistant for,
Copper Development Association
260 Madison Avenue
New York, New York 10016

Mail to: Heather R. Bjornson
Technology Sciences Group, Inc.
1150 18th Street, N.W.
Suite 1000
Washington, D.C. 20036

Subject: Antimicrobial Copper Alloys Group III
EPA Registration Number 82012- 3
Your Amendment Dated September 17th, 2009
EPA Received Date September 18th, 2009

The amendment referred to above, submitted in connection with under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to add new claims for effectiveness as a sanitizer against Enterococcus faecalis Vancomycin Resistant, is acceptable.

The submitted efficacy data (MRID 478595-01) support the use of the product, Copper Alloy C26000, as a sanitizer against Enterococcus faecalis Vancomycin Resistant in the presence of a 5% fetal bovine serum and 0.01% Triton X-100 organic soil load. Specifically, the product (i.e., surface) was known to be effective in killing greater than 99.9 percent of bacteria in 120 minutes. Neutralization confirmation testing met the acceptance criterion of growth with $1\log_{10}$ of the numbers control. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

The submitted efficacy data (MRID 478595-02) support the use of the product, Copper Alloy C26000, as a residual self-sanitizer against Enterococcus faecalis Vancomycin Resistant in the presence of a 5% fetal bovine serum and 0.01% Triton X-100 organic soil load. Specially, the product (i.e., surface) was shown to be effective in reducing the total number of organisms by at least 99.9 percent on the surface within/for prescribed exposure time. Neutralization confirmation testing met the acceptance criterion of growth within $1\log_{10}$ of the numbers control. Purity controls were reported as pure. Sterility controls did not show growth.

The submitted efficacy data (MRID 478595-03) support the use of the product, Copper Alloy C26000, as a continuous reduction sanitizer against Enterococcus faecalis Vancomycin Resistant in the presence of a 5% fetal bovine serum and 0.01% Triton X-100 organic soil load. Specifically, the product (i.e., surface) was shown to be effective in continuously reducing bacteria(by at least 90 percent) over a 24 hour inoculation and exposure time at ambient conditions. Neutralization confirmation testing met the acceptance criterion of growth with 1 $\log_{10}$ of the numbers control. Viability controls were positive for growth. Purity controls were reported a pure. Sterility controls did not show growth.

The proposed label for the product, Antimicrobial Copper Alloys Group III, claims that this surface, when cleaned regularly:

- Continuously reduces bacterial contamination, achieving 99.9% reduction within 2 hours of exposure
- Kills greater than 99.9% of gram-negative and gram-positive bacteria within 2 hours of exposure
- Delivers continuous and on-going antibacterial action, remaining effective in killing greater than 99.9% of bacteria within 2 hours
- Kills greater than 99.9% of bacteria within 2 hours, and continues to kill 99% of bacteria even after repeated contamination
- Helps inhibit the buildup and growth of bacteria within 2 hours of exposure between routing cleaning and sanitizing steps.

These claims, as they pertain to Enterococcous faecalis Vancomycin Resistant, are acceptable as they are supported by the submitted data.

A stamped copy of the labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration /reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these condition

If you have questions concerning this letter, please contact Karen M. Leavy at (703)-308-6237.

Sincerely,

DHE for

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510P)

Master Label containing:
Sublabel I: Complete Label
Sublabel II: Hang Tag Label

ANTIMICROBIAL COPPER ALLOYS GROUP III+

+NOTE: Product labels will bear the name of a copper alloy specified in the approved registration. Distributors may substitute a Product Brand Name in place of the name of the copper alloy on the label.

Active Ingredient:

Copper	82.6%
Other	17.4%
Total	100%

EPA Registration No. 82012-3
EPA Establishment No. *****

Made in the United States by *******
Distributed by *******

Net Contents: ******

ACCEPTED
with COMMENTS
EPA Letter Dated:

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 82012-3

Sublabel I: Complete Label

ANTIMICROBIAL COPPER ALLOYS GROUP III[+]

[+]NOTE: Product labels will bear the name of a copper alloy specified in the approved registration. Distributors may substitute a Product Brand Name in place of the name of the copper alloy on the label.

Laboratory testing has shown that when cleaned regularly:

[This surface continuously reduces bacterial* contamination, achieving 99.9% reduction within two hours of exposure.]

[This surface kills greater than 99.9% of Gram-negative and Gram-positive bacteria* within two hours of exposure.]

[This surface delivers continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within two hours.

[This surface kills greater than 99.9% of bacteria* within two hours, and continues to kill 99% of bacteria* even after repeated contamination.]

[This surface helps inhibit the buildup and growth of bacteria* within two hours of exposure between routine cleaning and sanitizing steps.]

* Testing demonstrates effective antibacterial activity against *Staphylococcus aureus*, *Enterobacter aerogenes*, Methicillin-Resistant *Staphylococcus aureus* (MRSA), *Escherichia coli* O157:H7, *Pseudomonas aeruginosa,* and Vancomycin – Resistant *Enterococcus faecalis (VRE).*

The use of a Copper Alloy surface is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces. The Copper Alloy surface material has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

* * * * *

ACCEPTED
with COMMENTS
EPA Letter Dated:

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 82012-3

Active Ingredient:	
Copper	82.6%
Other	17.4%
Total	100%

EPA Registration No. 82012-3
EPA Establishment No. *****

Made in the United States by *******
Distributed by *******

Net Contents: ******

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[The directions in bracketed text below may be included in an insert. If so, there will be a statement to see the insert for additional directions for use of the product.]

[Directions for Use in the insert also may include installation and operation instructions, user manuals, and similar instructional materials appropriate for the end use product. No additional pesticidal claims will be made as part of these materials.]

Proper Care and Use of Antimicrobial Copper Alloys: **The use of Antimicrobial Copper Alloys does not replace standard infection control procedures and good hygienic practices. Antimicrobial Copper Alloys surfaces must be cleaned and sanitized according to standard practice.** Health care facilities must maintain the product in accordance with infection control guidelines; users must continue to follow all current infection control practices, including those practices related to disinfection of environmental surfaces.

Copper Alloy surfaces may be subject to recontamination and the level of active bacteria at any particular time will depend on the frequency and timing of recontamination and cleanliness of the surface (among other factors). In order for the copper alloy surface to have proper antimicrobial effect, the product must be cleaned and maintained according to the directions included on this label.

This product must not be waxed, painted, lacquered, varnished, or otherwise coated.

Routine cleaning to remove dirt and filth is necessary for good sanitation and to assure the effective antibacterial performance of the Antimicrobial Copper Alloy surface. Cleaning agents typically used for traditional touching surfaces are permissible; the appropriate cleaning agent depends on the type of soiling and the measure of sanitization required. [Normal tarnishing or wear of Antimicrobial Copper Alloy surfaces will not impair the antibacterial effectiveness of the product.]

This product can not be used for any direct food contact or food packaging uses.

[Antimicrobial Copper Alloys may be used in hospitals, other healthcare facilities, and various public, commercial, and residential buildings for the non-food contact surfaces listed below.] [The following statement will appear on the label if the use involves potential exposure to outdoor conditions: Surfaces that may be exposed to outdoor environmental conditions (*e.g.*, handrails, shopping carts, child seats and ATM machines) are not representative of indoor laboratory test conditions, and therefore, may impart reduced efficacy if not cleaned when visibly soiled.]

ACCEPTED
with COMMENTS
EPA Letter Dated:

Healthcare Facilities

- Bedrails, footboards
- Over-bed tables

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 82012-3

- Bed-side tables in hospitals, extended care facilities, senior housing etc. (knobs, pulls, handles; surfaces)
- Handrails, (corridor/hallways) (Senior housing), automatic door push plates
- Stair rails, handrails, tubular railing, and supports, rail fittings T's, elbows and brackets
- Bedrails, assistance rails,
- Toilet safety rails
- Carts
    - Hospital carts (table surfaces, handles, legs)
    - Computer carts
    - Record carts
    - Phlebotomy carts
    - Other Carts (tables/surfaces, shelving, railings, handles, pulls)
- Equipment carts (horizontal surfaces, frames, handles)
- Door push plates, kick plates, mop plates, stretcher plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Water fountains: bubbler head, drain strainer, handle
- Alcohol sanitizer dispenser, handle
- Paper towel holders, facial tissue holders, toilet paper holders
- Air hand dryer, controls and push buttons on air hand dryers
- Hydrotherapy tanks (whirlpool tanks): shells, covers, headrests, drain fittings (outer surfaces without water contact)
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Panic bars on emergency room doors
- Towel bars
- Showerheads
- Countertops and tabletops (non-food use only)
- Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Closures
- Vertical locking arms
- Vertical cover guards
- Protection bars
- Light switches, switch plates
- Visitor chairs: armrests, metal frames
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Floor tiles
- Ceiling tiles (non-porous)
- Wall tiles

ACCEPTED
with COMMENTS
EPA Letter Dated:
FEB - 1
... the Federal Insecticide, ...icide, and Rodenticide Act as ... ended, for the pesticide, ...gistered under EPA Reg. No. 82012-3

- Instrument handles
  Medical equipment knobs, pulls and handles for:
  - Drug delivery systems
  - Monitoring systems
  - Hospital beds
  - Office equipment
  - Operating room equipment
  - Stands and fixtures

  Types of knobs: *e.g.*, Prong, fluted, knurled, push/pull, T-handle, tapered, and ball knobs
- Intravenous (IV) poles, bases, hangers, clips
- Trays (instruments, non-food contact)
- Pans (bed)
- Walkers, wheelchair handles, and tubular components
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise and rehabilitation equipment, handles, bars
- Physical therapy equipment: physical therapy tables, treatment chairs and portable taping tables
- Chairs (shower chairs, patient chairs, visitor chairs): rails, backs, legs, seats
- Lighting products: X-ray illuminators, operating rooms, patient examination rooms, surgical suites, and reading lamps for hospital rooms and assisted living facilities etc. Components can include bases, arms, housings, handles, hinges)
- Headwall systems: the unit themselves, outlet covers, knobs and dials, lighting units (lamp housings and adjustable arms), CRT monitors with rotating knobs and levers and adjustments. Baskets, monitor housings, knobs, baskets, tables, IV poles
- Critical care cart: Table top, drawer, drawer pull, lock, copper wire baskets for storage of equipment and charts.
- Bedside lavatory: sink, faucet, handles, drawer pulls, toilet seat, toilet seat cover, toilet handle, door and cabinet facings, counter tops
- Medical records: Chart holders, clipboards, filing systems
- Storage Shelving: wire shelving etc. for medical supplies
- Grab handles on privacy curtains
- Lids of laundry hampers, trash canisters, and other containers
- Bedside pitchers
- Closet rods and hangers
- Television controls: knobs, buttons, remote
- Monitor (television, computer, etc.) housing
- Cup Holder
- Toothbrush holder
- Soap holder
- Magazine rack
- Signage
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Bracelets

ACCEPTED
with COMMENTS
EPA Letter Dated:

FEB - 9

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 82012-3

- Pens
- Badge clips
- Name tags
- Patient gown snaps
- Window sills, pulls and locks
- Electrical wallplates

Community Facilities (including various public and commercial buildings)

- Shopping cart handles, child seats, handrails
- Cash registers: housing, keypads
- ATM machines: keys, housing
- Gym/Health club lockers, locker handles, locker shelving, trainers' tables,
- Ice and water dispensers (outer surfaces without water contact)
- Elevator: handrail, control panel, buttons, interior walls, floor tiles, exterior call button plate
- Paper towel dispensers. Housing itself, (turn) handle, (push) handle
- Soap holder
- Soap dispenser (wall mounted): push bar and dispenser itself
- Soap dispenser (sitting on counter): dispenser housing itself, push mechanism
- Toilet paper dispenser (housing)
- Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)
- Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)
- Light switches, switch plates
- Lids of laundry hampers, trash canisters, and other containers
- Magazine rack
- Signage
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Bracelets
- Badge clips
- Name tags
- Vending machines (non-food contact only)
- Window sills
- Electrical wallplates
- Clip boards
- Office supplies: paper clips, staplers, tape dispensers

Residential Buildings (including homes, apartments, apartment buildings and other residences)

- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)

- Bedrails, footboards
- Handrails
- Stair rails
- Door push plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Paper towel holders, facial tissue holders, toilet paper holders
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Towel bars
- Showerheads
- Countertops and tabletops
- Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Light switches, switch plates
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- Floor tiles
- Ceiling tiles (non-porous)
- Wall tiles
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise equipment, handles, bars
- Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)
- Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)
- Television control knobs and buttons
- Lids of laundry hampers, trash canisters, and other containers
- Bedside pitchers
- Closet rods and hangers
- Television remote
- Cup Holder
- Toothbrush holder
- Soap holder
- Magazine rack
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Window sills
- Electrical wallplates
- Baby cribs: rails, fittings, brackets, supports
- Bowl stands
- Office supplies: paper clips, staplers, tape dispensers
- Monitor (television, computer, etc.) housing

Mass Transit Facilities

- Handrails
- Stair rails, tubular railing, and supports; elbows and brackets
- Door push plates, kick plates
- Door handles, door knobs (outer touch surfaces)
- Grab bars and handles
- Tiles: wall, floor, ceiling (non-porous)
- Chairs and benches: rails, backs, legs, seats
- Window sills, pulls, and handles
- Signage
- Vending machines (non-food contact only)

Other

- Play area equipment (indoor only): bars, handles, chains, push plates, handrails, stair rails and risers, wheels, knobs, flooring
- Chapel pews
- Eye glass frames and protective eye wear
- Pens
- Combs
- Ashtrays

STORAGE AND DISPOSAL

Antimicrobial Copper Alloys should be disposed in a responsible manner, including recycling.

WARRANTY STATEMENT

If used as intended, Antimicrobial Copper Alloys are wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.

ACCEPTED
with COMMENTS
EPA Letter Dated:
FEB - 9 2010
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended. for the pesticide, registered under EPA Reg. No. 82012-3

Sublabel II: Hang Tag Label

FRONT

Made from

Antimicrobial Copper Alloys Group III

Active Ingredient:

Copper	82.6%
Other	17.4%
Total	100.0%

See Back Panel for Directions for Use

ACCEPTED
with COMMENTS
EPA Letter Dated:

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 82012-3

BACK

ANTIMICROBIAL COPPER ALLOYS GROUP III

Laboratory testing has shown that when cleaned regularly:

- This surface continuously reduces bacteria* contamination, achieving 99.9% reduction within 2 hours of exposure.
- This surface kills greater than 99.9% of Gram-negative and Gram-positive bacteria* within 2 hours of exposure.
- This surface delivers continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within 2 hours.
- This surface kills greater than 99.9% of bacteria* within two hours and continues to kill 99% of bacteria* even after repeated contaminations.
- This surface helps inhibit the buildup and growth of bacteria* within 2 hours of exposure between routine cleaning and sanitizing steps.

* Testing demonstrates effective antibacterial activity against *Staphylococcus aureus*, *Enterobacter aerogenes*, Methicillin-Resistant *Staphylococcus aureus* (MRSA), *Escherichia coli* O157:H7, *Pseudomonas aeruginosa, and* Vancomycin – Resistant *Enterococcus faecalis (VRE)*.

The use of this product is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces. This surface has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Proper Care and Use. The use of this product does not replace standard infection control procedures and good hygienic practices. This product must be cleaned and sanitized according to standard practice. Healthcare facilities must maintain the product in accordance with infection control guidelines; users must continue to follow all current infection control practices, including those practices related to disinfection of environmental surfaces.

This surface may be subject to recontamination and the level of active bacteria at any particular time will depend on the frequency and timing of recontamination and cleanliness of the surface (among other factors). In order for this product to have proper antimicrobial effect, the product must be cleaned and maintained according to the directions included on this label.

This product must not be waxed, painted, lacquered, varnished, or otherwise coated.

Routine cleaning to remove dirt and filth is necessary for good sanitation and to assure the effective antibacterial performance of this surface. Cleaning agents typically used for traditional touching surfaces are permissible; the appropriate cleaning agent depends on the type of soiling and the measure of sanitization required. Normal tarnishing or wear of Antimicrobial Copper Alloy surfaces will not impair the antibacterial effectiveness of the product.

This product can not be used for any direct food contact or food packaging uses.

Surfaces that may be exposed to outdoor environmental conditions (e.g., handrails, shopping carts, child seats and ATM machines) are not representative of indoor laboratory test conditions, and therefore, may impart reduced efficacy if not cleaned when visibly soiled.

STORAGE AND DISPOSAL

Antimicrobial Copper Alloys Group III should be disposed in a responsible manner, including recycling.

WARRANTY STATEMENT

If used as intended, Antimicrobial Copper Alloys are wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.

EPA Reg. No. 82012-3 EPA Est. No. 82012-NY-001
Manufactured by: Copper Development Association, 260 Madison Ave., NY, NY 10016-2401

Antimicrobial Copper Alloys may be used in hospitals, other healthcare facilities, and various public, commercial, and residential buildings for the non-food contact surfaces listed below.

Surfaces that may be exposed to outdoor environmental conditions (*e.g.*, handrails, shopping carts, child seats and ATM machines) are not representative of indoor laboratory test conditions, and therefore, may impart reduced efficacy if not cleaned when visibly soiled.

Healthcare Facilities

- Bedrails, footboards
- Over-bed tables
- Bed-side tables in hospitals, extended care facilities, senior housing etc. (knobs, pulls, handles; surfaces)
- Handrails, (corridor/hallways) (Senior housing), automatic door push plates
- Stair rails, handrails, tubular railing, and supports, rail fittings T's, elbows and brackets
- Bedrails, assistance rails,
- Toilet safety rails
- Carts
    - Hospital carts (table surfaces, handles, legs)
    - Computer carts
    - Record carts
    - Phlebotomy carts
    - Other Carts (tables/surfaces, shelving, railings, handles, pulls)
- Equipment carts (horizontal surfaces, frames, handles)
- Door push plates, kick plates, mop plates, stretcher plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Water fountains: bubbler head, drain strainer, handle
- Alcohol sanitizer dispenser, handle
- Paper towel holders, facial tissue holders, toilet paper holders
- Air hand dryer, controls and push buttons on air hand dryers
- Hydrotherapy tanks (whirlpool tanks): shells, covers, headrests, drain fittings (outer surfaces without water contact)
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Panic bars on emergency room doors
- Towel bars
- Showerheads
- Countertops and tabletops (non-food use only)
- Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Closures
- Vertical locking arms
- Vertical cover guards
- Protection bars
- Light switches, switch plates
- Visitor chairs: armrests, metal frames
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Floor tiles
- Ceiling tiles (non-porous)
- Wall tiles
- Instrument handles

    Medical equipment knobs, pulls and handles for:

    - Drug delivery systems
    - Monitoring systems
    - Hospital beds
    - Office equipment
    - Operating room equipment
    - Stands and fixtures

    Types of knobs: *e.g.*, Prong, fluted, knurled, push/pull, T-handle, tapered, and ball knobs
- Intravenous (IV) poles, bases, hangers, clips
- Trays (instruments, non-food contact)
- Pans (bed)
- Walkers, wheelchair handles, and tubular components
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise and rehabilitation equipment, handles, bars

ACCEPTED
with COMMENTS
EPA Letter Dated:

FEB - 9 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 82012-3

- Physical therapy equipment: physical therapy tables, treatment chairs and portable taping tables
- Chairs (shower chairs, patient chairs, visitor chairs): rails, backs, legs, seats
- Lighting products: X-ray illuminators, operating rooms, patient examination rooms, surgical suites, and reading lamps for hospital rooms and assisted living facilities etc. Components can include bases, arms, housings, handles, hinges)
- Headwall systems: the unit themselves, outlet covers, knobs and dials, lighting units (lamp housings and adjustable arms), CRT monitors with rotating knobs and levers and adjustments. Baskets, monitor housings, knobs, baskets, tables, IV poles
- Critical care cart: Table top, drawer, drawer pull, lock, copper wire baskets for storage of equipment and charts.
- Bedside lavatory: sink, faucet, handles, drawer pulls, toilet seat, toilet seat cover, toilet handle, door and cabinet facings, counter tops
- Medical records: Chart holders, clipboards, filing systems
- Storage Shelving: wire shelving etc. for medical supplies
- Grab handles on privacy curtains
- Lids of laundry hampers, trash canisters, and other containers
- Bedside pitchers
- Closet rods and hangers
- Television controls: knobs, buttons, remote
- Monitor (television, computer, etc.) housing
- Cup Holder
- Toothbrush holder
- Soap holder
- Magazine rack
- Signage
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Bracelets
- Pens
- Badge clips
- Name tags
- Patient gown snaps
- Window sills, pulls and locks
- Electrical wallplates

Community Facilities (including various public and commercial buildings)

- Shopping cart handles, child seats, handrails
- Cash registers: housing, keypads
- ATM machines: keys, housing
- Gym/Health club lockers, locker handles, locker shelving, trainers' tables,
- Ice and water dispensers (outer surfaces without water contact)
- Elevator: handrail, control panel, buttons, interior walls, floor tiles, exterior call button plate
- Paper towel dispensers. Housing itself, (turn) handle, (push) handle
- Soap holder
- Soap dispenser (wall mounted): push bar and dispenser itself
- Soap dispenser (sitting on counter): dispenser housing itself, push mechanism
- Toilet paper dispenser (housing)
- Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)
- Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)
- Light switches, switch plates
- Lids of laundry hampers, trash canisters, and other containers
- Magazine rack
- Signage
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Bracelets
- Badge clips
- Name tags
- Vending machines (non-food contact only)
- Window sills
- Electrical wallplates
- Clip boards
- Office supplies: paper clips, staplers, tape dispensers

ACCEPTED
with COMMENTS
EPA Letter Dated:

FEB - 9 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 82012-3

Residential Buildings (including homes, apartments, apartment buildings and other residences)

- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Bedrails, footboards
- Handrails
- Stair rails
- Door push plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Paper towel holders, facial tissue holders, toilet paper holders
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Towel bars
- Showerheads
- Countertops and tabletops
- Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Light switches, switch plates
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- Floor tiles
- Ceiling tiles (non-porous)
- Wall tiles
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise equipment, handles, bars
- Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)
- Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)
- Television control knobs and buttons
- Lids of laundry hampers, trash canisters, and other containers
- Bedside pitchers
- Closet rods and hangers
- Television remote
- Cup Holder
- Toothbrush holder
- Soap holder
- Magazine rack
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Window sills
- Electrical wallplates
- Baby cribs: rails, fittings, brackets, supports
- Bowl stands
- Office supplies: paper clips, staplers, tape dispensers
- Monitor (television, computer, etc.) housing

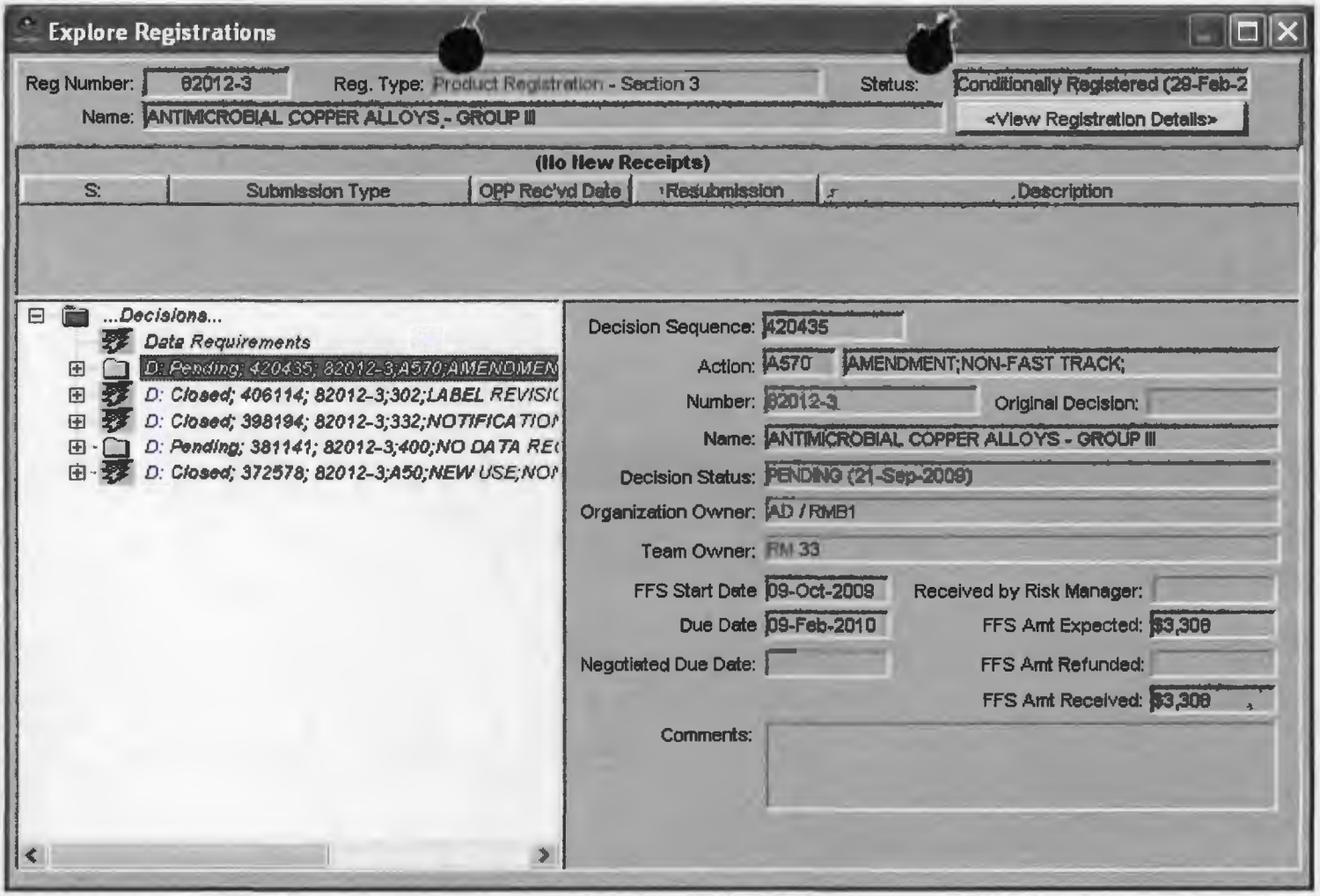
ACCEPTED
with COMMENTS
EPA Letter Dated:
FEB - 0 2010
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended for the pesticide, registered under EPA Reg. No. 82012-3

Mass Transit Facilities

- Handrails
- Stair rails, tubular railing, and supports; elbows and brackets
- Door push plates, kick plates
- Door handles, door knobs (outer touch surfaces)
- Grab bars and handles
- Tiles: wall, floor, ceiling (non-porous)
- Chairs and benches: rails, backs, legs, seats
- Window sills, pulls, and handles
- Signage
- Vending machines (non-food contact only)

Other

- Play area equipment (indoor only): bars, handles, chains, push plates, handrails, stair rails and risers, wheels, knobs, flooring
- Chapel pews
- Eye glass frames and protective eye wear
- Pens
- Combs
- Ashtrays


Explore Registrations
Reg Number: 82012-3
Reg. Type: Product Registration - Section 3
Status: Conditionally Registered (29-Feb-2
Name: ANTIMICROBIAL COPPER ALLOYS - GROUP III
<View Registration Details>
(No New Receipts)
S:
Submission Type
OPP Rec'vd Date
Resubmission
Description
...Decisions...
Data Requirements
D: Pending; 420435; 82012-3;A570;AMENDMEN
D: Closed; 406114; 82012-3;302;LABEL REVISI
D: Closed; 398194; 82012-3;332;NOTIFICATIO
D: Pending; 381141; 82012-3;400;NO DATA RE
D: Closed; 372578; 82012-3;A50;NEW USE;NO
Decision Sequence: 420435
Action: A570 AMENDMENT;NON-FAST TRACK;
Number: 82012-3
Original Decision:
Name: ANTIMICROBIAL COPPER ALLOYS - GROUP III
Decision Status: PENDING (21-Sep-2009)
Organization Owner: AD / RMB1
Team Owner: RM 33
FFS Start Date 09-Oct-2009
Received by Risk Manager:
Due Date 09-Feb-2010
FFS Amt Expected: $3,300
Negotiated Due Date:
FFS Amt Refunded:
FFS Amt Received: $3,300
Comments:

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 9-18-09

Experts In-Processing Signature: MF HARRINGTON Date 9-23-09 Fee Paid: Yes ✓

Division management contacted on issues No_____Yes_____Date_____

EPA Reg. Number: 82012-3	EPA Receipt Date: 9-18-09

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	**yes** X	**no**			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	**yes**	**no**			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	**Data Matrix** (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	**yes** X	**no**			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to** http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	**Is the data package consistent with PR Notice 86-5** (link to PRN 86-5)	X		
8	**Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)**			X
9	**If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)**			X
10	**Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

Passed 86-5 Review. MRID 478595

Inerts cleared for non food use JD

MRID 478595

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. <u>All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.</u>

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Script for Rejection Phone calls

Contact Name: Heather Bjornson
Phone #: 202-828-8945
Email: hbjornson@tsgusa.com

First Call/Initials:	**Second Call/Initials:**
Date: 9/24	**Date:**
Time: 12:40	**Time:**

This is _____, **EPA contractor.**

I'm calling regarding your submission in support of
82012-6, 2, 1, 3, 5.

We have found the following deficiencies regarding:
PR Notice 86.5: Yes or No
Volume/Study Title:

Volume/Study Title:

Volume/Study Title:

Additional volumes continued on back of page: Yes or No

Application Package: Yes or No
Inerts that can't be confirmed - CAS# [redacted]
[redacted]
Missing Certification (selective method)

These deficiencies have been approved by EPA.
The corrections can be faxed to 703-305-5060/Attn: _____.

Second Call/Email:
If we do not receive the corrections by _____, **we will process your submission, accordingly. Please direct all future calls and correspondence to the appropriate EPA Risk Manager.**

Inert ingredient information may be entitled to confidential treatment

RE: Amended Registrations 82012-1, -2, -3, -5, -6

Heather Bjornson to: Jennifer Drobish 09/24/2009 05:04 PM

Cc: Sree Nair

Jennifer -
The Certification with Respect to Data Citation forms are signed and attached.

Regards,
Heather R. Bjornson
Technology Sciences Group, Inc.
1150 18th Street NW., Ste. 1000
Washington DC 20036
Tel.: 202-828-8945
Fax: 202-872-0745

-----Original Message-----
From: Drobish.Jennifer@epamail.epa.gov
[mailto:Drobish.Jennifer@epamail.epa.gov]
Sent: Thursday, September 24, 2009 12:40 PM
To: Heather Bjornson
Cc: nair.sree@epa.gov
Subject: Amended Registrations 82012-1, -2, -3, -5, -6

Ms Bjornson

This is Jennifer Drobish, EPA contractor. I am writing in regards to you submissions in support of the amended registrations of 82012-1, -2, -3, -5, -6. We have found a deficiency with these application packages. Each application package is missing the Certification with Respect to Citation of Data (EPA form 8570-34). These forms can either be faxed to me at 703-305-5060/Attn: Jennifer Drobish or emailed to me at drobish.jennifer@epa.gov

Thank you
Jennifer Drobish
EPA Contractor
703-305-1671

Certificates with Respect to data citation - 9-17-09.pdf

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 21, 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-420435
EPA File Symbol or Registration Number: 82012-3
Product Name: ANTIMICROBIAL COPPER ALLOYS - GROUP III
EPA Receipt Date: 18-Sep-2009
EPA Company Number: 82012
Company Name: COPPER DEVELOPMENT ASSOCIATION (CDA)

COPPER DEVELOPMENT ASSOCIATION (CDA)
260 MADISON AVENUE
NEW YORK, NY 10016

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A570

AMENDMENT;NON-FAST TRACK;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6432.

Sincerely,
Teresa Downs
Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{858444:~

This package includes the following

- ○ New Registration
- ◉ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ◉ AD
- ○ BPPD
- ○ RD

Risk Mgr. 33

Receipt No. S-	858444
EPA File Symbol/Reg. No.	82012-3
Pin-Punch Date:	9/18/2009

☐ This item is NOT subject to FFS action.

Action Code:

Requested: A570

Granted: A570

Amount Due: $ 3308.

Parent/Child Decisions:

▣ Inert Cleared for Intended Use ▣ Uncleared Inert in Product

Reviewer: Mitchell/Carlisle/McKelvin Date: 9/21/09

Remarks: 3rd batch

Online Payment

Step 3: Confirm Payment **1 | 2 | 3**

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 24VOVHBO
Agency Tracking ID: 74080830841
Transaction Date and Time: 09/16/2009 17:32 EDT

Payment Summary

Address Information

Account Holder Name: Heather R. Bjornson
Billing Address: 1150 18th Street NW
Billing Address 2: Ste. 1000
City: Washington
State / Province: DC
Zip / Postal Code: 20036
Country: USA

Account Information

Card Type: American Express
Card Number: **********1436
Decision Number:
Registration Number: 82012-3

Should be 82012-31.

Payment Information

Payment Amount: $3,308.00
Transaction Date and Time: 09/16/2009 17:32 EDT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

January 5, 2010

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 82012-3, Antimicrobial Copper Alloys, Group III; DP Barcode: 370913

From: Tajah Blackburn, PhD
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

1/5/10

Thru: Emily Mitchell, Branch Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Marshall Swindell PM 33/ Karen Leavy
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Copper Development Association
260 Madison Ave
New York, NY 10016

Formulation from the Label:

Active Ingredient(s)	% by wt.
Copper	82.6%
Other Ingredients	17.4%
Total	100.0%

I BACKGROUND

The product, Antimicrobial Copper Alloys Group III (EPA Reg. No. 82012-3), is a registered copper alloy with bactericidal reduction properties for use in household, commercial, and hospital or medical environments. The applicant requested to amend the registration of this product to add new claims for effectiveness as a sanitizer against *Enterococcus faecalis* Vancomycin Resistant. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant's representative to EPA (dated September 17, 2009), three studies (MRID 478595-01 through 478595-03), Statements of No Data Confidentiality Claims for all three studies, and the proposed label.

II USE DIRECTIONS

The product is a copper alloy surface that reduces bacterial contamination. Surfaces, items, and objects made with this product may include assistance rails and hand rails, bedrails, benches, cart handles, carts, ceiling tiles, chairs, countertops, dispensers, door kick plates, door push plates, exercise equipment, faucets, floor tiles, footboards, hamper lids, handles, holders, hydrotherapy tanks, instrument handles, knobs, latches, lockers, pans, pulls, racks, showerheads, sinks, storage shelving, tabletops (including over-bed tables and bed-side tables), toilet and urinal hardware, towel bars, trash canister lids, trays, wall tiles, and water fountains. Directions on the proposed label provide proper care and use instructions. Routine cleaning to remove dirt and filth is necessary for good sanitation and to assure the effective antibacterial performance of the copper alloy surface.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Copper Alloy Surfaces as a Sanitizer

The effectiveness of copper alloy surfaces as sanitizers must be supported by data that show that the product (i.e., surface) will substantially reduce the numbers of test bacteria. Tests must be performed against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Results must show a bacterial reduction of at least 99.9 percent over the carrier quantitation control. The carrier quantitation control must yield a minimum geometric mean of 2.0×10^4 CFU/carrier. Claims for additional bacteria will be considered only if acceptable sanitizer efficacy is demonstrated for *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Products that are represented as residual self-sanitizers and/or continuous reduction sanitizers must demonstrate acceptable sanitizer efficacy before additional claims are considered. Agency standards and required label language are presented in EPA's "Test Method for Efficacy of Copper Alloy Surfaces as a Sanitizer."

Residual Self-Sanitizing Activity of Copper Alloy Surfaces

The effectiveness of copper alloy surfaces to provide residual self-sanitizing activity must be supported by data that show that the product (i.e., surface) will

substantially reduce the number of test bacteria. An initial sanitizer evaluation, a simulated wear-and-re-inoculation evaluation, and a final sanitizer evaluation must be performed. Tests must be performed against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Results must show a reduction of the total number of organisms by at least 99.9 percent on the surface within/for the prescribed exposure time. The control plates must show a minimum of 2×10^4 CFU/carrier for the test to be considered valid. Claims for additional bacteria will be considered only if acceptable sanitizer efficacy is demonstrated for *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Products that are represented as residual self-sanitizers and/or continuous reduction sanitizers must demonstrate acceptable sanitizer efficacy before additional claims are considered. Agency standards and required label language are presented in EPA's "Test Method for Residual Self-Sanitizing Activity of Copper Alloy Surfaces."

Copper Alloy Surfaces as a Continuous Reduction Sanitizer

The effectiveness of copper alloy surfaces to provide continuous reduction of bacterial contamination must be supported by data that show that the product (i.e., surface) will substantially reduce the number of test bacteria. Tests must be performed against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Results must show a bacterial reduction of at least 90 percent over the carrier quantitation control at all recovery times over the 24-hour inoculation and exposure period. The carrier quantitation control must yield a minimum geometric mean of 2.0×10^4 CFU/carrier. Claims for additional bacteria will be considered only if acceptable sanitizer efficacy is demonstrated for *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Products that are represented as residual self-sanitizers and/or continuous reduction sanitizers must demonstrate acceptable sanitizer efficacy before additional claims are considered. Agency standards and required label language are presented in EPA's "Test Method for the Continuous Reduction of Bacterial Contamination on Copper Alloy Surfaces."

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 478595-01 "Test Method for Efficacy of Copper Alloy Surfaces as a Sanitizer," Test Organism: *Enterococcus faecalis* Vancomycin Resistant (ATCC 51575), for Copper Alloy C26000, by Amy S. Jeske. Study conducted at ATS Labs. Study completion date – April 16, 2009. Project Number A07378.

This study was conducted against *Enterococcus faecalis* Vancomycin Resistant (ATCC 51575). Two lots (Lot Nos. 4237310 and 4237430) of the product, Copper Alloy C26000, were tested. Testing followed procedures outlined in EPA's "Test Method for Efficacy of Copper Alloy Surfaces as a Sanitizer." The laboratory report referenced the Sanitizer Test from DIS/TSS-10 and the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (ASTM E1153). The product was received ready-to-use. A culture of the challenge microorganism was prepared in accordance with the EPA method. The organic soil load was comprised of 5% fetal bovine serum and 0.01% Triton X-100. Five copper alloy carriers (1" x 1") were cut from each product lot, cleaned, and sterilized. Three sterile stainless steel carriers (1" x 1") were used as a control. Each carrier was inoculated with 20.0 µL of a ~48 hour old suspension of test organism. The inoculum was spread to within 1/8 inch of the edges

of each carrier. The carriers were dried for 28 minutes at 20°C at 15% relative humidity. Following the 120-minute exposure time, each carrier was placed into a sterile jar containing 20 mL of Letheen Broth. Each neutralizer jar was sonicated for 5 minutes to suspend any survivors from the carriers and rotated to mix. Within 1 hour after carrier sonication, serial dilutions of the neutralized solutions were prepared. One (1.00) mL aliquots of the 10^0 to 10^{-4} dilutions were plated in duplicate on tryptic soy agar with 5% sheep's blood. All plates were incubated for ~46.5 hours at 35-37°C. Following incubation, the plates were visually enumerated. Controls included those for inoculum count, carrier quantitation, purity, sterility, viability, neutralization confirmation, and antibiotic resistance.

Note: Antibiotic resistance of *Enterococcus faecalis* Vancomycin Resistant (ATCC 51575) was verified on a representative culture. The laboratory performed a Kirby Bauer Susceptibility assay. *Staphylococcus aureus* (ATCC 25923) was the control organism. The measured zone of inhibition (i.e., 10 mm) confirmed antibiotic resistance of *Enterococcus faecalis* Vancomycin Resistant (ATCC 51575) to vancomycin. See page 9 and Table 7 of the laboratory report.

Note: Protocol deviations/amendments reported in the study were reviewed.

2. MRID 478595-02 "Test Method for Residual Self-Sanitizing Activity of Copper Alloy Surfaces," Test Organism: *Enterococcus faecalis* Vancomycin Resistant (ATCC 51575), for Copper Alloy C26000, by Amy S. Jeske. Study conducted at ATS Labs. Study completion date – April 17, 2009. Project Number A07402.

This study was conducted against *Enterococcus faecalis* Vancomycin Resistant (ATCC 51575). Two lots (Lot Nos. 4237310 and 4237430) of the product, Copper Alloy C26000, were tested. Testing followed procedures outlined in EPA's "Test Method for Residual Self-Sanitizing Activity of Copper Alloy Surfaces." The laboratory report referenced the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (ASTM E1153). The product was received ready-to-use. Cultures of the challenge microorganism were prepared in accordance with the EPA method. The organic soil load was comprised of 5% fetal bovine serum and 0.01% Triton X-100. Four copper alloy carriers (1" x 1") per sanitizer (initial or final) were cut from each product lot, cleaned, and sterilized. Four sterile stainless steel carriers (1" x 1") per sanitizer (initial or final) were used as a control.

For the initial sanitizer evaluation, each carrier was inoculated with 20.0 µL of the 48 hour old "initial sanitizer" organism suspension. The inoculum was spread to within 1/8 inch of the edges of each carrier. The carriers were dried for 27 minutes at 35-37°C at 40% relative humidity. Immediately after drying, the 120-minute exposure period began. The carriers were held for 120 minutes at 20°C at 11% relative humidity. Following exposure, each carrier was placed into a sterile jar containing 30 mL of Letheen Broth. Each neutralizer jar was sonicated for 3-5 minutes in a sonicating water bath. The samples then were mixed on an orbital shaker for 3-4 minutes at 250 rpm. Serial dilutions of the neutralized solutions were prepared in 9 mL of sterile Butterfield's Buffer. Within 30 minutes of transfer to the neutralizer, one (1.00) mL aliquots of the 10^0 to 10^{-2} dilutions for the test samples were plated in duplicate on tryptic soy agar with 5% sheep's blood. [Within 30 minutes of transfer to the neutralizer, one (1.00) mL aliquots

of the 10^{-2} to 10^{-4} dilutions for the control samples were plated in duplicate on tryptic soy agar with 5% sheep's blood.] All plates were incubated for ~46.25 hours at 35-37°C. Following incubation, the number of surviving test organisms per carrier was determined.

For the inoculation, simulated wear, and re-inoculation evaluation, each carrier was inoculated with 10.0 µL of the 23.5 hour old "simulated wear" organism suspension. The inoculum was spread to within 1/8 inch of the edges of each carrier. The carriers were dried for ~30 minutes at ambient conditions. Each carrier was subjected to twelve (12) wear cycles, alternating wet and dry wear. [A wear cycle equals one pass to the left and a return pass to the right on the Gardner scrubber with an abrasion boat fitted with a foam liner and dry (or moist) cotton cloth.] At least 15 minutes after each wear cycle, each carrier was re-inoculated as previously described and dried for at least 30 minutes at ambient conditions.

For the final sanitizer evaluation, each carrier was inoculated with 20.0 µL of the ~49.5 hour old "final sanitizer" organism suspension. The inoculum was spread to within 1/8 inch of the edges of each carrier. The carriers were dried for 35 minutes at 35-37°C at 40% relative humidity. Immediately after drying, the 120-minute exposure period began. The carriers were held for 120 minutes at 20°C at 24% relative humidity. Following exposure, each carrier was placed into a sterile jar containing 30 mL of Letheen Broth. Each neutralizer jar was sonicated for 3-5 minutes in a sonicating water bath. The samples then were mixed on an orbital shaker for 3-4 minutes at 250 rpm. Serial dilutions of the neutralized solutions were prepared in 9 mL of sterile Butterfield's Buffer. Within 30 minutes of transfer to the neutralizer, one (1.00) mL aliquots of the 10^{0} to 10^{-2} dilutions for the test samples were plated in duplicate on tryptic soy agar with 5% sheep's blood. [Within 30 minutes of transfer to the neutralizer, one (1.00) mL aliquots of the 10^{-2} to 10^{-4} dilutions for the control samples were plated in duplicate on tryptic soy agar with 5% sheep's blood.] All plates were incubated for ~45.25 hours at 35-37°C. Following incubation, the number of surviving test organisms per carrier was determined. Controls included those for inoculum count, purity, sterility, viability, neutralization confirmation, and antibiotic resistance.

Note: The test was performed in compliance with EPA Good Laboratory Practice (GLP) regulations (40 CFR Part 160) with the following exception: "The result of the viability control was inadvertently not recorded at the time the test was read as required by 40 CFR Part 160.130(e)."

Note: The laboratory reported a failed study set up on February 18, 2009. In the study, the final sanitizer stainless steel control carriers failed to meet the acceptance criterion of 2.0×10^{4} CFU/carrier. The laboratory did not accept the assay. These data were not used to evaluate efficacy of the product. Testing was repeated on March 2, 2009. See page 8 and Attachment I of the laboratory report.

Note: Antibiotic resistance of *Enterococcus faecalis* Vancomycin Resistant (ATCC 51575) was verified on a representative culture. The laboratory performed a Kirby Bauer Susceptibility assay. *Staphylococcus aureus* (ATCC 25923) was the control organism. The measured zone of inhibition (i.e., 10 mm) confirmed antibiotic resistance of *Enterococcus faecalis* Vancomycin Resistant (ATCC 51575) to vancomycin. See page 9 and Table 8 of the laboratory report.

Note: Protocol deviations/amendments reported in the study were reviewed.

3. MRID 478595-03 "Test Method for the Continuous Reduction of Bacterial Contamination on Copper Alloy Surfaces," Test Organism: *Enterococcus faecalis* Vancomycin Resistant (ATCC 51575), for Copper Alloy C26000, by Amy S. Jeske. Study conducted at ATS Labs. Study completion date – April 16, 2009. Project Number A07434.

This study was conducted against *Enterococcus faecalis* Vancomycin Resistant (ATCC 51575). Two lots (Lot Nos. 4237310 and 4237430) of the product, Copper Alloy C26000, were tested. Testing followed procedures outlined in EPA's "Test Method for the Continuous Reduction of Bacterial Contamination on Copper Alloy Surfaces." The laboratory report referenced the Sanitizer Test from DIS/TSS-10 and the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (ASTM E1153). The product was received ready-to-use. A culture of the challenge microorganism was prepared in accordance with the EPA method. The organic soil load was comprised of 5% fetal bovine serum and 0.01% Triton X-100. Five copper alloy carriers (1" x 1") per contact time were cut from each product lot, cleaned, and sterilized. Three sterile stainless steel carriers (1" x 1") per contact time were used as a control. Each carrier was inoculated with 10.0 µL of a ~47 hour old suspension of test organism. The initial inoculation represents time point 0. At 3, 6, 9, 12, 15, 18, and 21 hours, carrier sets not removed for quantitative recovery were re-inoculated. The inoculum was spread on the surface of each carrier. The carriers were dried for the duration of the exposure at ambient conditions. Sets of carriers were removed for quantitative recovery at 2, 6, 12, 18, and 24 hours. Each carrier was placed into a sterile jar containing 20 mL of Letheen Broth. Each neutralizer jar was sonicated for 5 minutes to suspend any survivors from the carriers and rotated to mix. Within 1 hour after carrier sonication, serial dilutions of the neutralized solutions were prepared. One (1.00) mL aliquots of the 10^0 to 10^{-4} dilutions were plated in duplicate on tryptic soy agar with 5% sheep's blood. All plates were incubated for ~49 hours at 35-37°C (which complies with the EPA method specification of 48±4 hours at 35-37°C). The plates were stored for 1 day at 2-8°C prior to examination. Following incubation and storage, the plates were visually enumerated. Controls included those for inoculum count, carrier quantitation, purity, sterility, viability, neutralization confirmation, and antibiotic resistance.

Note: Antibiotic resistance of *Enterococcus faecalis* Vancomycin Resistant (ATCC 51575) was verified on a representative culture. The laboratory performed a Kirby Bauer Susceptibility assay. *Staphylococcus aureus* (ATCC 25923) was the control organism. The measured zone of inhibition (i.e., 10 mm) confirmed antibiotic resistance of *Enterococcus faecalis* Vancomycin Resistant (ATCC 51575) to vancomycin. See page 9 and Table 7 of the laboratory report.

Note: Protocol deviations/amendments were reported.

V RESULTS

MRID No.	Test Organism	Lot No.	Hours	Survivors (CFU/carrier)	Microbes Initially Present (CFU/carrier)	Percent Reduction
478595-01	*Enterococcus faecalis* Vancomycin Resistant	4237310	2	$<2 \times 10^1$	2.57×10^6	>99.9
		4237430	2	$<2 \times 10^1$	2.57×10^6	>99.9
478595-02	*Enterococcus faecalis* Vancomycin Resistant	Initial Sanitizer				
		4237310	2	$<3.02 \times 10^1$	4.17×10^6	>99.9
		4237430	2	$<3.02 \times 10^1$	4.17×10^6	>99.9
		Final Sanitizer				
		4237310	2	$<3.02 \times 10^1$	3.31×10^5	>99.9
		4237430	2	$<3.02 \times 10^1$	3.31×10^5	>99.9
478595-03	*Enterococcus faecalis* Vancomycin Resistant	4237310	2	$<2.00 \times 10^1$	2.69×10^6	>99.9
			6	$<2.00 \times 10^1$	3.31×10^6	>99.9
			12	$<2.00 \times 10^1$	8.51×10^6	>99.9
			18	$<2.00 \times 10^1$	9.12×10^6	>99.9
			24	5.13×10^3	8.71×10^6	99.9
		4237430	2	$<2.00 \times 10^1$	2.69×10^6	>99.9
			6	$<2.00 \times 10^1$	3.31×10^6	>99.9
			12	$<2.00 \times 10^1$	8.51×10^6	>99.9
			18	$<2.00 \times 10^1$	9.12×10^6	>99.9
			24	3.24×10^3	8.71×10^6	99.9

VI CONCLUSIONS

1. The submitted efficacy data (MRID 478595-01) support the use of the product, Copper Alloy C26000, as a sanitizer against *Enterococcus faecalis* Vancomycin Resistant in the presence of a 5% fetal bovine serum and 0.01% Triton X-100 organic soil load. Specifically, the product (i.e., surface) was shown to be effective in killing greater than 99.9 percent of bacteria in 120 minutes. Neutralization confirmation testing met the acceptance criterion of growth within 1 $\log_{10}$ of the numbers control. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

2. The submitted efficacy data (MRID 478595-02) support the use of the product, Copper Alloy C26000, as a residual self-sanitizer against *Enterococcus faecalis* Vancomycin Resistant in the presence of a 5% fetal bovine serum and 0.01% Triton X-100 organic soil load. Specifically, the product (i.e., surface) was shown to be effective

in reducing the total number of organisms by at least 99.9 percent on the surface within/for the prescribed exposure time. Neutralization confirmation testing met the acceptance criterion of growth within 1 $\log_{10}$ of the numbers control. Purity controls were reported as pure. Sterility controls did not show growth.

3. The submitted efficacy data (MRID 478595-03) support the use of the product, Copper Alloy C26000, as a continuous reduction sanitizer against *Enterococcus faecalis* Vancomycin Resistant in the presence of a 5% fetal bovine serum and 0.01% Triton X-100 organic soil load. Specifically, the product (i.e., surface) was shown to be effective in continuously reducing bacteria (by at least 90 percent) over a 24-hour inoculation and exposure time at ambient conditions. Neutralization confirmation testing met the acceptance criterion of growth within 1 $\log_{10}$ of the numbers control. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

VII RECOMMENDATIONS

1. The proposed label for the product, Antimicrobial Copper Alloys Group III, claims that this surface, when cleaned regularly:

- Continuously reduces bacterial contamination, achieving 99.9% reduction within 2 hours of exposure
- Kills greater than 99.9% of gram-negative and gram-positive bacteria within 2 hours of exposure
- Delivers continuous and on-going antibacterial action, remaining effective in killing greater than 99.9% of bacteria within 2 hours
- Kills greater than 99.9% of bacteria within 2 hours, and continues to kill 99% of bacteria even after repeated contamination
- Helps inhibit the buildup and growth of bacteria within 2 hours of exposure between routing cleaning and sanitizing steps.

These claims, as they pertain to *Enterococcus faecalis* Vancomycin Resistant, are acceptable as they are supported by the submitted data.

2. The product data matrix lists all MRIDs for the three types of test on one line, and as a result the pests are not listed. It is recommended that the applicant revise their data matrix with a line for each test and pest so that future questions of efficacy can be quickly verified.

3. The proposed label does not list the ATCC numbers for the organisms tested, and neither does the data matrix. ATCC numbers must be recorded on either the master label (with the organisms listed, or a separate reference page not for printing) or on the data matrix.

DATA PACKAGE BEAN SHEET

Date: 22-Oct-2009

Decision #: 420435
DP #: (370913)
PRIA
Parent DP #:
Submission #: 858444

* * * Registration Information * * *

Registration: 82012-3 - ANTIMICROBIAL COPPER ALLOYS - GROUP III

Company: 82012 - COPPER DEVELOPMENT ASSOCIATION (CDA)

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828

Risk Manager Reviewer: Karen Leavy KLEAVY

Sent Date: _____ Calculated Due Date: 09-Feb-2010 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A570) AMENDMENT;NON-FAST TRACK;

Ingredients: 022501, Copper as elemental(82.6%)

* * * Data Package Information * * *

Expedite: ◯ Yes ● No Date Sent: 22-Oct-2009 Due Back: _____

DP Ingredient: 022501, Copper as elemental

DP Title: _____

CSF Included: ◯ Yes ● No Label Included: ● Yes ◯ No Parent DP #: _____

Assigned To	Date In	Date Out	
Organization: AD / PSB			Last Possible Science Due Date: 10-Jan-2010
Team Name: EET			Science Due Date: 08-Jan-2010
Reviewer Name:			Sub Data Package Due Date: 08-Jan-2010
Contractor Name:			

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Please review the submitted efficacy studies, Test Method of Copper Alloy Surfaces as a Sanitizer(MRID No. 478595-01), Test Method of Self-Sanitizing Activity of Copper Alloys(MRID No. 478595-02), Test Method of Continuous Reduction of Bacterial Contamination(MRID No. 478595-03), PRIA, Action Code A570, Admin. Due Date 02/09/10, EET Due Date 01/08/10

DATA PACKAGE BEAN SHEET

Date: 22-Oct-2009

Decision #: 420435
DP #: (370913)
PRIA
Parent DP #:
Submission #: 858444

* * * Registration Information * * *

Registration: 82012-3 - ANTIMICROBIAL COPPER ALLOYS - GROUP III

Company: 82012 - COPPER DEVELOPMENT ASSOCIATION (CDA)

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828

Risk Manager Reviewer: Karen Leavy KLEAVY

Sent Date: _____ Calculated Due Date: 09-Feb-2010 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A570) AMENDMENT;NON-FAST TRACK;

Ingredients: 022501, Copper as elemental(82.6%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 22-Oct-2009 Due Back: _____

DP Ingredient: 022501, Copper as elemental

DP Title: _____

CSF Included: ○ Yes ● No Label Included: ● Yes ○ No Parent DP #: _____

Assigned To		Date In	Date Out	
Organization:	AD / PSB			Last Possible Science Due Date: 10-Jan-2010
Team Name:	EET			Science Due Date: 08-Jan-2010
Reviewer Name:				Sub Data Package Due Date: 08-Jan-2010
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Please review the submitted efficacy studies, Test Method of Copper Alloy Surfaces as a Sanitizer(MRID No. 478595-01), Test Method of Self-Sanitizing Activity of Copper Alloys(MRID No. 478595-02), Test Method of Continuous Reduction of Bacterial Contamination(MRID No. 478595-03), PRIA, Action Code A570, Admin. Due Date 02/09/10, EET Due Date 01/08/10

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Copper Development Association, 260 Madison Ave., NY, NY 10016-2401 212-251-7234	EPA Registration Number/File Symbol 82012-3
Active Ingredient(s) and/or representative test compound(s) Copper (metallic)	Date September 17, 2009
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor, non-food	Product Name Antimicrobial Copper Alloys Group III

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☑ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Heather R Bjor	9/17/2009	Heather Bjornson, Regulatory Consultant

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date January 20, 2010	EPA Reg No./File Symbol 82012-3	Page 1 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group 3	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	46999301 47259201	Copper Development Association	Own	
830.1600	Description of Materials Used to Produce Product	46999301	Copper Development Association	Own	
830.1620	Description of Production Process	46999301	Copper Development Association	Own	
830.1650	Description of Formulation Process	46999301	Copper Development Association	Own	
830.1670	Discussion of Formation of Impurities	46999301	Copper Development Association	Own	
830.1700	Preliminary Analysis	46999301 47160802	Copper Development Association	Own	
830.1750	Certified Limits	46999301	Copper Development Association	Own	
830.1800	Enforcement Analytical Method	46999301	Copper Development Association	Own	
830.1900	Submittal of Standards	46999301	Copper Development Association	Own	

Signature	Name and Title	Date
Heather R Bjornson	Heather Bjornson, Regulatory Agent	1/20/2010

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date January 20, 2010	EPA Reg No./File Symbol 82012-3	Page 2 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group 3	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6302	Color				Not required OPPTS 830.1000
830.6303	Physical State	47160801	Copper Development Association	Own	
830.6304	Odor				Not required OPPTS 830.1000
830.6313	Stability to Temperature, Metals, and Metal Ions				Not required OPPTS 830.1000
830.6314	Oxidation/Reduction	47160801	Copper Development Association	Own	
830.6315	Flammability	47160801	Copper Development Association	Own	
830.6316	Explodability	47160801	Copper Development Association	Own	
830.6317	Storage Stability	47160801	Copper Development Association	Own	
830.6319	Miscibility	47160801	Copper Development Association	Own	
830.6320	Corrosion Characteristics	47160801	Copper Development Association	Own	
830.6321	Dielectric Breakdown Voltage	47160801	Copper Development Association	Own	
830.7000	pH	47160801	Copper Development Association	Own	
830.7050	UV/Visible Absorption				Not required OPPTS 830.1000
830.7100	Viscosity	47160801	Copper Development Association	Own	

Signature	Name and Title	Date
Heather Bjornson	Heather Bjornson, Regulatory Agent	1/20/2010

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date January 20, 2010	EPA Reg No./File Symbol 82012-3	Page 3 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group 3	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7200	Melting Point/Melting Range				Not required OPPTS 830.1000
830.7220	Boiling Point/Boiling Range				Not required OPPTS 830.1000
830.7300	Density/Relative Density/Bulk Density	47160801	Copper Development Association	Own	
830.7370	Dissociation Constants in Water				Not required OPPTS 830.1000
830.7550	Partition Coefficient (n-octanol/water)				Not required OPPTS 830.1000
830.7840	Water Solubility				Not required OPPTS 830.1000
830.7950	Vapor Pressure				Not required OPPTS 830.1000

Signature	Name and Title	Date
Heather R Bjornson	Heather Bjornson, Regulatory Agent	1/20/2010

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date January 20, 2010	EPA Reg No./File Symbol 82012-3	Page 4 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group 3	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute Oral Toxicity - Rats	46999302	Copper Development Association	Own	
870.1100	Acute Oral Toxicity - Mice	46999302	Copper Development Association	Own	
870.1200	Acute Dermal Toxicity	46999302	Copper Development Association	Own	
870.1300	Acute Inhalation Toxicity	46999302	Copper Development Association	Own	
870.2400	Acute Eye Irritation	46999302	Copper Development Association	Own	
870.2500	Acute Dermal Irritation	46999302	Copper Development Association	Own	
870.2600	Skin Sensitization	46999302	Copper Development Association	Own	
870.3150	90-Day Oral Toxicity - Dogs	46999302	Copper Development Association	Own	
870.3465	90-Day Oral Toxicity - Rats	46999302	Copper Development Association	Own	
870.3700	Prenatal Developmental Toxicity - Rabbits	46999302	Copper Development Association	Own	
870.3700	Prenatal Developmental Toxicity - Rats	46999302	Copper Development Association	Own	
870.3800	Reproduction and Fertility Effects - 2 Gen	46999302	Copper Development Association	Own	
870.4100	Chronic Feeding, Dog	46999302	Copper Development Association	Own	
870.4100	Chronic Feeding, Rat	46999302	Copper Development Association	Own	
870.5100	Bacterial Reverse Mutation (Ames)Test	46999302	Copper Development Association	Own	
870.	Other Mutagenicity	46999302	Copper Development Association	Own	
870.7485	Metabolism and Pharmacokinetics - Rat	46999302	Copper Development Association	Own	

Signature	Name and Title	Date
Heather R Bjornson	Heather Bjornson, Regulatory Agent	1/20/2010

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date January 20, 2010	EPA Reg No./File Symbol **82012-3**	Page 5 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group 3	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.2000	Hard Surface Sanitizer Assay S. aureus (ATCC 6538), E. aerogenes (ATCC) 13048)	46999306	Copper Development Association	OWN	
810.2000	Hard Surface Sanitizer Assay MRS, aureus (ATCC 33592), E. coli (ATCC 35150), P. aeruginosa (ATCC 15442)	46999307	Copper Development Association	OWN	
810.2000	Hard Surface Sanitizer Assay S. aureus (ATCC 6538), E. aerogenes (ATCC) 13048)	46999310	Copper Development Association	OWN	
810.2000	Hard Surface Sanitizer Assay S. aureus (ATCC 6538), E. aerogenes (ATCC) 13048)	46999312	Copper Development Association	OWN	
810.2000	Hard Surface Sanitizer Assay VRE. faecalis (ATCC 51575)	47859501	Copper Development Association	OWN	
810.2000	Residual Self-sanitizer Assay S. aureus (ATCC 6538), E. aerogenes (ATCC)	46999308	Copper Development Association	OWN	
810.2000	Residual Self-sanitizer Assay MRS, aureus (ATCC 33592), E. coli (ATCC 35150), P. aeruginosa (ATCC 15442)	46999309	Copper Development Association	OWN	
810.2000	Residual Self-sanitizer Assay VRE. faecalis (ATCC 51575)	47859502	Copper Development Association	OWN	
810.2000	Repeat Challenge Assay S. aureus (ATCC 6538), E. aerogenes (ATCC 13048)	46999304	Copper Development Association	OWN	
810.2000	Repeat Challenge Assay MRS, aureus (ATCC 33592), E. coli (ATCC 35150), P. aeruginosa (ATCC 15442)	76999305	Copper Development Association	OWN	
810.2000	Repeat Challenge Assay S. aureus (ATCC 6538), E. aerogenes (ATCC 13048)	4699311	Copper Development Association	OWN	
810.2000	Repeat Challenge Assay S. aureus (ATCC 6538), E. aerogenes (ATCC 13048)	46999312	Copper Development Association	OWN	
810.2000	Repeat Challenge Assay VRE. faecalis (ATCC 51575)	47859503	Copper Development Association	OWN	

Signature	Name and Title	Date
Heather R Bjornson	Heather Bjornson, Regulatory Agent	1/20/2010

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date January 20, 2010	EPA Reg No./File Symbol 82012-3	Page 1 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group 3	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	

Signature	Name and Title	Date
Heather R Bjornson	Heather Bjornson, Regulatory Agent	1/20/2010

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date January 20, 2010	EPA Reg No./File Symbol 82012-3	Page 2 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group 3	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Not required OPPTS 830.1000
			Copper Development Association	Own	
					Not required OPPTS 830.1000
					Not required OPPTS 830.1000
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
					Not required OPPTS 830.1000
			Copper Development Association	Own	

Signature	Name and Title	Date
Heather B Bjornson	Heather Bjornson, Regulatory Agent	1/20/2010

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date January 20, 2010	EPA Reg No./File Symbol 82012-3	Page 3 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group 3	
Ingredient Copper (Metallic)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Not required OPPTS 830.1000
					Not required OPPTS 830.1000
			Copper Development Association	Own	
					Not required OPPTS 830.1000
					Not required OPPTS 830.1000
					Not required OPPTS 830.1000
					Not required OPPTS 830.1000

Signature	Name and Title	Date
Heather Bjornson	Heather Bjornson, Regulatory Agent	1/20/2010

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date January 20, 2010	EPA Reg No./File Symbol 82012-3	Page 4 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group 3	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	
			Copper Development Association	Own	

Signature	Name and Title	Date
Heather R Bjo	Heather Bjornson, Regulatory Agent	1/20/2010

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date January 20, 2010	EPA Reg No./File Symbol 82012-3	Page 5 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group 3	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	

Signature	Name and Title	Date
Heather R Bjor	Heather Bjornson, Regulatory Agent	1/20/2010

TECHNOLOGY SCIENCES GROUP INC

WASHINGTON
1150 18th Street, N.W.
Suite 1000
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

SACRAMENTO
712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

CANADA
275 Slater Street
Suite 900
Ottawa, Ontario
K1P 5H9
Telephone 613 247-6285
Fax 613 236-3754

E-mail tsg@tsgusa.com
http://www.tsgusa.com

September 17, 2009

Marshall Swindell, Team 33
Office of Pesticide Programs
US Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Copper Development Association
Antimicrobial Copper Alloys Group III
EPA Reg. Nos. 82012-3
PRIA Category A570 – Amendment requiring data submission

Dear Mr. Swindell:

On behalf of the Copper Development Association (CDA), Technology Sciences Group, Inc., submits the enclosed label amendment to add an additional public health pest. You will find the following:

1) Application form,
2) Revised data matrices,
3) One redline version of the label,
4) Three clean copies of the label,
5) PRIA pre-payment receipt (Pay.gov tracking ID: 24VOVHBO; Agency tracking ID: 74080830841),
6) Transmittal document,
7) Date volumes 2 through 4 (refer to the transmittal document for specific information).

If you have any questions, please contact me at 202-828-8945 or by e-mail, hbjornson@tsgusa.com.

Sincerely,

Heather R. Bjornson
Regulatory Consultant, Copper Development Association

cc: H. Michels, CDA
J. Green, Kelley, Drye, Collier, Shannon

VOLUME 1 OF 4 OF SUBMISSION

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Copper Development Association Inc.
260 Madison Avenue
New York, NY 10016

REGULATORY ACTION:

Submission of efficacy data to support a label amendment for Antimicrobial Copper Alloys Group III (EPA Reg. No.: 82012-3).

TRANSMITTAL DATE:

September 17, 2009

LIST OF SUBMITTED STUDIES:

MRID NUMBER	VOLUME NUMBER	EPA STUDY TITLE	GUIDELINE NUMBER
	1 of 4	(Transmittal Document)	----------
	2 of 4	Efficacy of Copper Alloy Surfaces as a Sanitizer; Project No.A07378	810. 2700
	3 of 4	Residual Self-Sanitizing Activity of Copper Alloy Surfaces; Project No. A07402	810.2700
	4 of 4	Continuous Reduction of Bacterial Contamination; Project No. A07434	810.2700

COMPANY NAME: Copper Development Association Inc.

COMPANY OFFICIAL: Heather R. Bjornson, Regulatory Consultant

COMPANY CONTACT:

Heather R. Bjornson, Regulatory Consultant
Technology Sciences Group, Inc.
1150 18th Street, N.W. Ste.1000
Washington, DC 20036
(202) 828-8963

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☑ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
82012-3	Marshall Swindell	☑ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
Antimicrobial Copper Alloys Group III	33	

5. Name and Address of Applicant *(Include ZIP Code)*

Copper Development Association Inc.
260 Madison Avenue
New York, NY 10016

☐ *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☑ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Finel printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This label amendment is to add a public health organism and corresponding claims.

PRIA Category A570 - Amendment requiring data submission. PRIA pre-payment - Pay.gov Tracking ID: 24VOVHBO; Agency tracking ID: 74080830841.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☑ No	☐ Yes ☑ No	☐ Yes ☑ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☑ Other (Specify) none
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☑ Label ☐ Container	NA- no container	☑

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☑ Other Attached to Bill of Lading

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

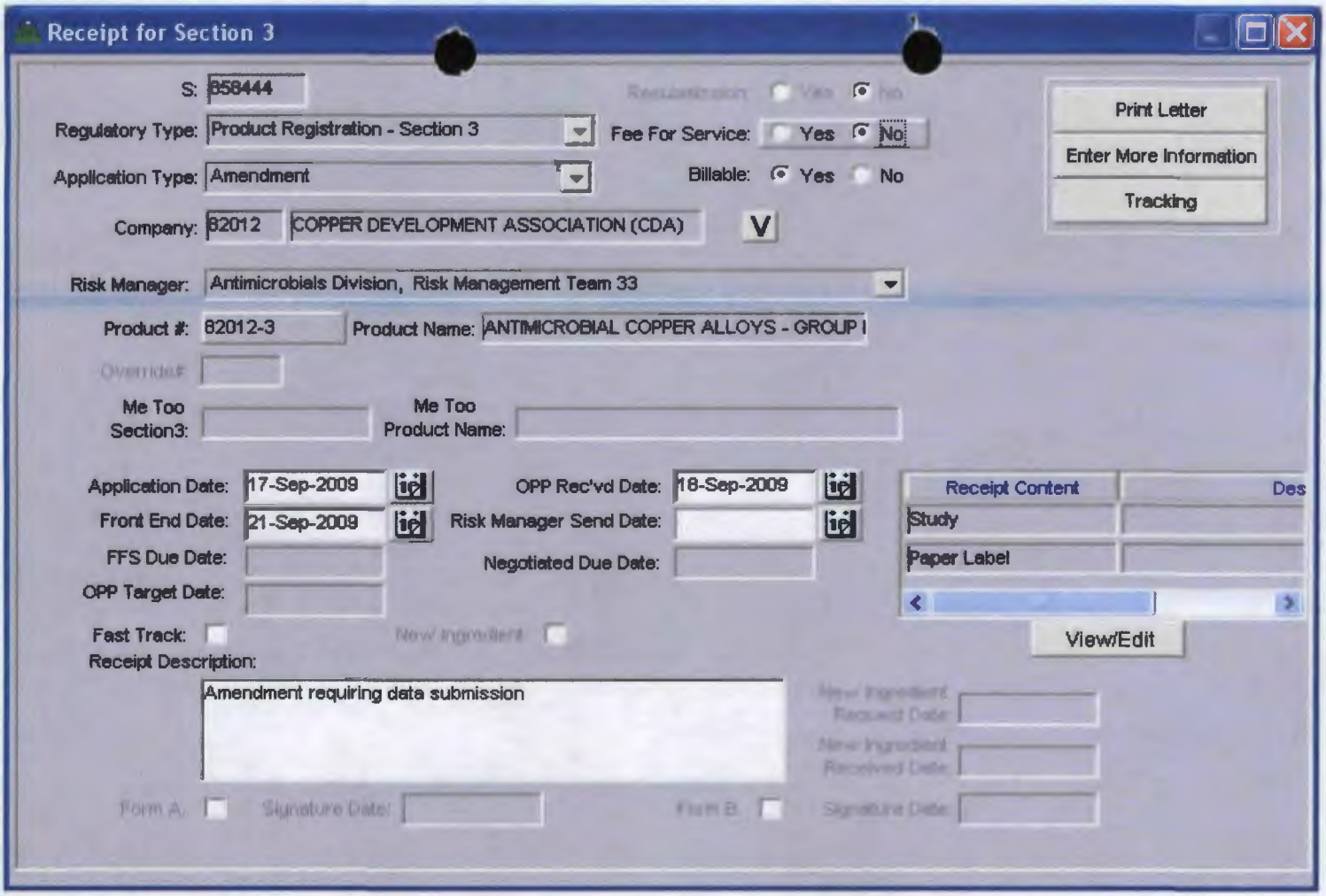
Name	Title	Telephone No. (Include Area Code)
Heather R. Bjornson, Technology Sciences Group, Inc.	Regulatory Consultant	(202) 828-8945

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	
Heather R. Bj	Regulatory Consultant to Copper Development Assoc. Inc.	
4. Typed Name	**5. Date**	
Heather R. Bjornson	September 17, 2009	


Receipt for Section 3
S: 858444
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Amendment
Billable: Yes No
Company: 82012 COPPER DEVELOPMENT ASSOCIATION (CDA)
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 33
Product #: 82012-3
Product Name: ANTIMICROBIAL COPPER ALLOYS - GROUP I
Override#
Me Too Section3:
Me Too Product Name:
Application Date: 17-Sep-2009
OPP Rec'vd Date: 18-Sep-2009
Front End Date: 21-Sep-2009
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Study
Paper Label
Fast Track:
New Ingredient
View/Edit
Receipt Description:
Amendment requiring data submission
New Ingredient Received Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 22, 2009

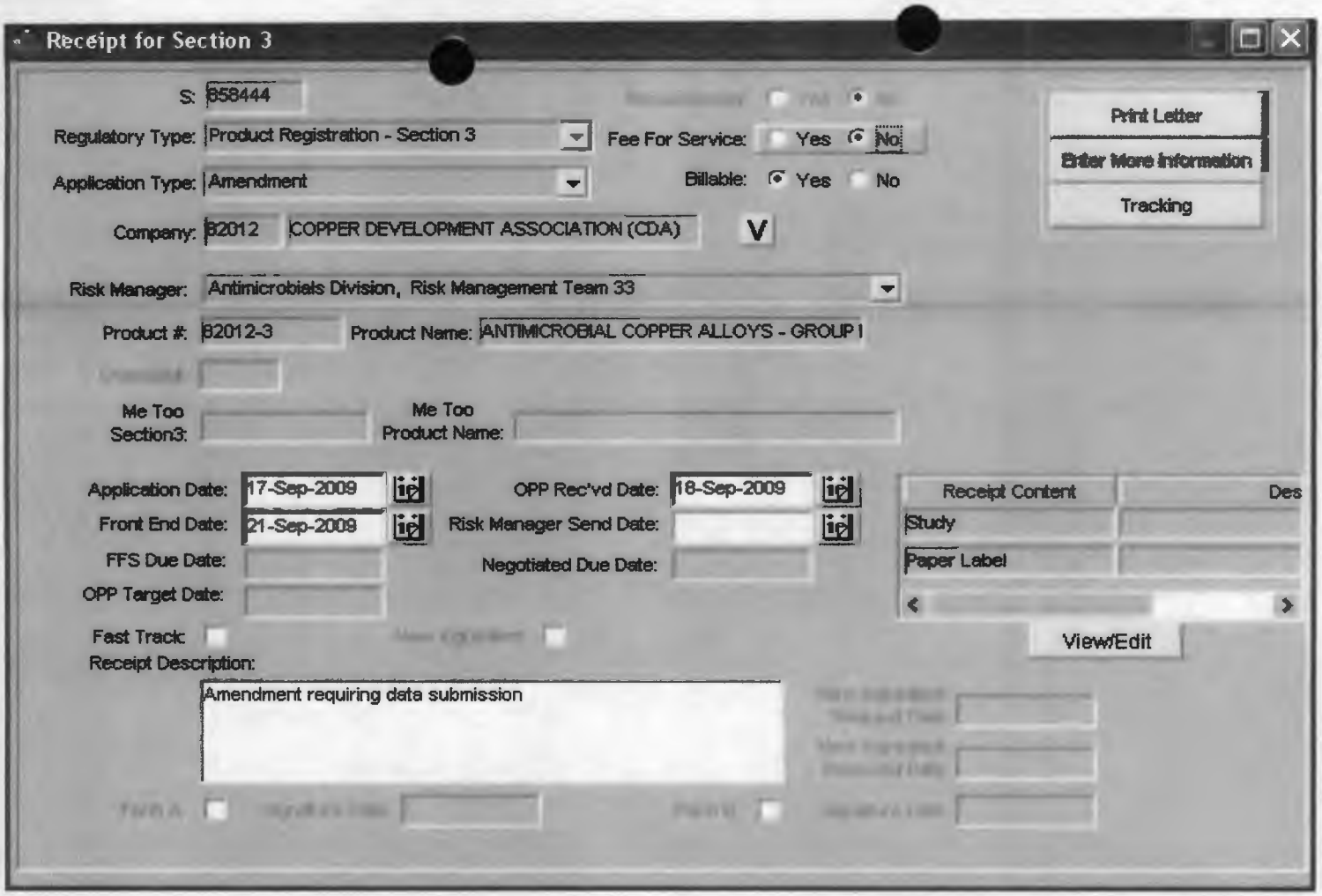
OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

COPPER DEVELOPMENT ASSOCIATION (CDA)
3050 K STREET, N.W., SUITE 400
WASHINGTON, DC 20007-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 18-SEP-09. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.


Receipt for Section 3
S: 858444
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Amendment
Billable: Yes No
Company: 32012 COPPER DEVELOPMENT ASSOCIATION (CDA)
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 33
Product #: 32012-3
Product Name: ANTIMICROBIAL COPPER ALLOYS - GROUP I
Me Too Section3:
Me Too Product Name:
Application Date: 17-Sep-2009
OPP Rec'vd Date: 18-Sep-2009
Front End Date: 21-Sep-2009
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Study
Paper Label
Fast Track:
View/Edit
Receipt Description:
Amendment requiring data submission

TECHNOLOGY SCIENCES GROUP INC

WASHINGTON
1150 18th Street, N.W.
Suite 1000
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

SACRAMENTO
712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

CANADA
275 Slater Street
Suite 900
Ottawa, Ontario
K1P 5H9
Telephone 613 247-6285
Fax 613 236-3754

E-mail tsg@tsgusa.com
http://www.tsgusa.com

September 17, 2009

Marshall Swindell, Team 33
Office of Pesticide Programs
US Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Copper Development Association
Antimicrobial Copper Alloys Group III
EPA Reg. Nos. 82012-3
PRIA Category A570 – Amendment requiring data submission

Dear Mr. Swindell:

On behalf of the Copper Development Association (CDA), Technology Sciences Group, Inc., submits the enclosed label amendment to add an additional public health pest. You will find the following:

1) Application form,
2) Revised data matrices,
3) One redline version of the label,
4) Three clean copies of the label,
5) PRIA pre-payment receipt (Pay.gov tracking ID: 24VOVHBO; Agency tracking ID: 74080830841),
6) Transmittal document,
7) Date volumes 2 through 4 (refer to the transmittal document for specific information).

If you have any questions, please contact me at 202-828-8945 or by e-mail, hbjornson@tsgusa.com.

Sincerely,

Heather R. Bjornson
Regulatory Consultant, Copper Development Association

cc: H. Michels, CDA
J. Green, Kelley, Drye, Collier, Shannon

VOLUME 1 OF 4 OF SUBMISSION

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Copper Development Association Inc.
260 Madison Avenue
New York, NY 10016

REGULATORY ACTION:

Submission of efficacy data to support a label amendment for Antimicrobial Copper Alloys Group III (EPA Reg. No.: 82012-3).

TRANSMITTAL DATE:

September 17, 2009

LIST OF SUBMITTED STUDIES:

MRID NUMBER	VOLUME NUMBER	EPA STUDY TITLE	GUIDELINE NUMBER
	1 of 4	(Transmittal Document)	----------
478595-01	2 of 4	Efficacy of Copper Alloy Surfaces as a Sanitizer; Project No.A07378	810. 2700
478595-02	3 of 4	Residual Self-Sanitizing Activity of Copper Alloy Surfaces; Project No. A07402	810.2700
478595-03	4 of 4	Continuous Reduction of Bacterial Contamination; Project No. A07434	810.2700

COMPANY NAME: Copper Development Association Inc.

COMPANY OFFICIAL: Heather R. Bjornson, Regulatory Consultant

COMPANY CONTACT:

Heather R. Bjornson, Regulatory Consultant
Technology Sciences Group, Inc.
1150 18th Street, N.W. Ste.1000
Washington, DC 20036
(202) 828-8963

Memorandum

Date: 9/23/09

To: PM 33, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

21-Day Screen Completed by Contractor

21-Day Expires on 10-9-09

Jacket # 82012-3
MRID# 478595

Content Screen: Recommended to Pass/Fail

86-5 Review: Passed/Failed/NA

Transfer This Jacket to:

MARSHALL SWINDELL

Material to be added to a Mini-Jacket
(in the case where an e-Jacket exists)

3A42

Reg. No. 82012-3

Send to SIG: check box ☑

This material is:

- € ✓ New stamped-accepted label
- € New CSF
- € Notification
- € Final Printed Label
- € Other: _____

Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: Karen Leary

Phone: 308-6237 **Division:** AD

Date: 4/24/09

Current as of Wednesday, May 10, 2006

DECISION PKG. NO. 406114 SUBM. DUE DATE 05/07/09

SUBMISSION BAR CODE # 844259 REVIEWER (illegible)

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 82012-3 PM 33 ACTION CODE 302

DESCRIPTOR _____ **FQPA** ✓ **NFQPA** ____

[ ] CHILD RESISTANT PACKAGING: [ ] REQUIRED [ ] NOT REQUIRED

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL [ ] RESTRICTED USE

DATE ON APPLICATION	EPA RECEIVE DATE	PM RECEIVE DATE
02/04/09	02/06/09	02/09/09

METHOD OF SUPPORT

[ ] CITE-ALL [ ] SELECTIVE
[ ] NOT SUBMITTED [ ] N/A

FORMULATORS EXEMPTION

[ ] SUBMITTED [ ] NOT SUBMITTED
[ ] N/A

REVIEW(S) REQUESTED	DATA PACK #	DATE SENT	DUE DATE	DATE RETURNED
CHEMISTRY				
EFFICACY				
ACUTE TOX.				
RASSB TOX.				
ENVIRON. FATE				
FISH/WILDLIFE				
OTHER: _____ :				

STATUS _____

RESPONSE CODE 1115 RESPONSE DATE 4/21/09

SCIENCE GROUP	DIVISION	BRANCH	SECTION	CSF Y/N	LABEL Y/N
CHEMISTRY	AD	EASSB	CTT		
EFFICACY	AD	EASSB	EET		

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 21 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ms. Heather R. Bjornson
Regulatory Assistant for,
Copper Development Association
260 Madison Avenue
New York, New York 10016

Mail to: Heather R. Bjornson
Technology Sciences Group, Inc.
1150 18th Street, N.W.
Suite 1000
Washington, D.C. 20036

Subject: Antimicrobial Copper Alloys Group III
EPA Registration Number 82012- 3
Your Amendment Dated February 4th, 2009
EPA Received Date February 9th, 2009

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to add revise the product labeling by adding additional use sites to the product labeling is acceptable, provided you make the following changes:

Revise the labeling claim, "When cleaned regularly, Antimicrobial Copper Alloys kills .....after repeated contamination", to read as follows: "When cleaned regularly, Antimicrobial Copper Alloys kill greater thatn 99.9% of bacteria* within two hours, and continues to kill 99% of bacteria* even after repeated contamination."

The following use sites must be deleted where ever they appear on the product labeling and hang tag label:

Bedside pitchers
Toothbrush holder
Cup holder

These use sites are considered food contact surfaces.

A clear description of cup holder and bowl stand must be provided to the Agency before these claims can be accepted.

Provide the Agency with the frequency of times a parent, caregiver, and/or employee in a nursery would clean or follow cleaning procedures as per the use pattern of Baby cribs: rails, fittings, brackets, supports. These surfaces would have to be cleaned on a scheduled basis in order to comply with the Agency's labeling requirements for Copper Alloy products. Please note that the product claims continuous and ongoing bacterial action when scheduled cleaning practices and methods are followed.

A stamped copy of the labeling is enclosed for your records.

If you have questions concerning this letter, please contact Karen M. Leavy at (703)-308-6237.

Sincerely,

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510P)

Master Label containing:
Sublabel I: Complete Label
Sublabel II: Hang Tag Label

ANTIMICROBIAL COPPER ALLOYS GROUP III+

+NOTE: Product labels will bear the name of a copper alloy specified in the approved registration. Distributors may substitute a Product Brand Name in place of the name of the copper alloy on the label.

Active Ingredient:	
Copper	82.6%
Other	17.4%
Total	100%

EPA Registration No. 82012-3
EPA Establishment No. *****

Made in the United States by *******
Distributed by *******

Net Contents: ******

ACCEPTED
with COMMENTS
In EPA Letter Dated:
APR 21 2009

Under the Federal Insecticide, Fungicide, and [illegible] Act as amended, for the pesticide, registered under Reg. No. 82012-3

Sublabel I: Complete Label

ANTIMICROBIAL COPPER ALLOYS GROUP III[+]

[+]NOTE: Product labels will bear the name of a copper alloy specified in the approved registration. Distributors may substitute a Product Brand Name in place of the name of the copper alloy on the label.

Laboratory testing has shown that when cleaned regularly:

[This surface continuously reduces bacterial* contamination, achieving 99.9% reduction within two hours of exposure.]

[This surface kills greater than 99.9% of Gram-negative and Gram-positive bacteria* within two hours of exposure.]

[This surface delivers continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within two hours.

[This surface kills greater than 99.9% of bacteria* within two hours, and continues to kill 99% of bacteria* even after repeated contamination.]

[This surface helps inhibit the buildup and growth of bacteria* within two hours of exposure between routine cleaning and sanitizing steps.]

* Testing demonstrates effective antibacterial activity against *Staphylococcus aureus*, *Enterobacter aerogenes*, Methicillin-Resistant *Staphylococcus aureus* (MRSA), *Escherichia coli* O157:H7, and *Pseudomonas aeruginosa.*

The use of a Copper Alloy surface is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces. The Copper Alloy surface material has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

ACCEPTED
with COMMENTS
In EPA Letter Dated:
APR 21 2009
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under Reg. No. 82012-3

Active Ingredient:	
Copper	82.6%
Other	17.4%
Total	100%

EPA Registration No. 82012-3
EPA Establishment No. *****

Made in the United States by *******
Distributed by *******

Net Contents: ******

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[The directions in bracketed text below may be included in an insert. If so, there will be a statement to see the insert for additional directions for use of the product.]

[Directions for Use in the insert also may include installation and operation instructions, user manuals, and similar instructional materials appropriate for the end use product. No additional pesticidal claims will be made as part of these materials.]

Proper Care and Use of Antimicrobial Copper Alloys: **The use of Antimicrobial Copper Alloys does not replace standard infection control procedures and good hygienic practices. Antimicrobial Copper Alloys surfaces must be cleaned and sanitized according to standard practice.** Health care facilities must maintain the product in accordance with infection control guidelines; users must continue to follow all current infection control practices, including those practices related to disinfection of environmental surfaces.

Copper Alloy surfaces may be subject to recontamination and the level of active bacteria at any particular time will depend on the frequency and timing of recontamination and cleanliness of the surface (among other factors). In order for the copper alloy surface to have proper antimicrobial effect, the product must be cleaned and maintained according to the directions included on this label.

This product must not be waxed, painted, lacquered, varnished, or otherwise coated.

Routine cleaning to remove dirt and filth is necessary for good sanitation and to assure the effective antibacterial performance of the Antimicrobial Copper Alloy surface. Cleaning agents typically used for traditional touching surfaces are permissible; the appropriate cleaning agent depends on the type of soiling and the measure of sanitization required. [Normal tarnishing or wear of Antimicrobial Copper Alloy surfaces will not impair the antibacterial effectiveness of the product.]

This product can not be used for any direct food contact or food packaging uses.

[Antimicrobial Copper Alloys may be used in hospitals, other healthcare facilities, and various public, commercial, and residential buildings for the non-food contact surfaces listed below.] [The following statement will appear on the label if the use involves potential exposure to outdoor conditions: Surfaces that may be exposed to outdoor environmental conditions (*e.g.*, handrails, shopping carts, child seats and ATM machines) are not representative of indoor laboratory test conditions, and therefore, may exhibit reduced efficacy if not cleaned when visibly soiled.]

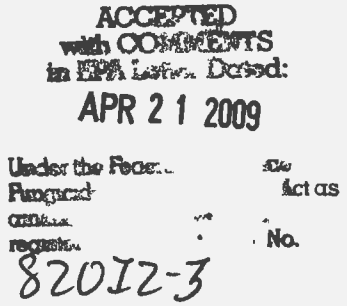
ACCEPTED
With
APR 21 2009
Under the Federal ... cide ... Act as ...
... No. 82012-3

Healthcare Facilities

- Bedrails, footboards
- Over-bed tables
- Bed-side tables in hospitals, extended care facilities, senior housing etc. (knobs, pulls, handles; surfaces)

- Handrails, (corridor/hallways) (Senior housing), automatic door push plates
- Stair rails, handrails, tubular railing, and supports, rail fittings T's, elbows and brackets
- Bedrails, assistance rails,
- Toilet safety rails
- Carts
  - Hospital carts (table surfaces, handles, legs)
  - Computer carts
  - Record carts
  - Phlebotomy carts
  - Other Carts (tables/surfaces, shelving, railings, handles, pulls)
- Equipment carts (horizontal surfaces, frames, handles)
- Door push plates, kick plates, mop plates, stretcher plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Water fountains: bubbler head, drain strainer, handle
- Alcohol sanitizer dispenser, handle
- Paper towel holders, facial tissue holders, toilet paper holders
- Air hand dryer, controls and push buttons on air hand dryers
- Hydrotherapy tanks (whirlpool tanks): shells, covers, headrests, drain fittings (outer surfaces without water contact)
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Panic bars on emergency room doors
- Towel bars
- Showerheads
- Countertops and tabletops (non-food use only)
- Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Closures
- Vertical locking arms
- Vertical cover guards
- Protection bars
- Light switches, switch plates
- Visitor chairs: armrests, metal frames
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Floor tiles
- Ceiling tiles (non-porous)
- Wall tiles
- Instrument handles

Medical equipment knobs, pulls and handles for:



- Drug delivery systems
- Monitoring systems
- Hospital beds
- Office equipment
- Operating room equipment
- Stands and fixtures

Types of knobs: *e.g.*, Prong, fluted, knurled, push/pull, T-handle, tapered, and ball knobs

- Intravenous (IV) poles, bases, hangers, clips
- Trays (instruments, non-food contact)
- Pans (bed)
- Walkers, wheelchair handles, and tubular components
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise and rehabilitation equipment, handles, bars
- Physical therapy equipment: physical therapy tables, treatment chairs and portable taping tables
- Chairs (shower chairs, patient chairs, visitor chairs): rails, backs, legs, seats
- Lighting products: X-ray illuminators, operating rooms, patient examination rooms, surgical suites, and reading lamps for hospital rooms and assisted living facilities etc. Components can include bases, arms, housings, handles, hinges)
- Headwall systems: the unit themselves, outlet covers, knobs and dials, lighting units (lamp housings and adjustable arms), CRT monitors with rotating knobs and levers and adjustments. Baskets, monitor housings, knobs, baskets, tables, IV poles
- Critical care cart: Table top, drawer, drawer pull, lock, copper wire baskets for storage of equipment and charts.
- Bedside lavatory: sink, faucet, handles, drawer pulls, toilet seat, toilet seat cover, toilet handle, door and cabinet facings, counter tops
- Medical records: Chart holders, clipboards, filing systems
- Storage Shelving: wire shelving etc. for medical supplies
- Grab handles on privacy curtains
- Lids of laundry hampers, trash canisters, and other containers
- [redacted]
- Closet rods and hangers
- Television controls: knobs, buttons, remote
- Monitor (television, computer, etc.) housing
- [redacted]
- Soap holder
- Magazine rack
- Signage
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Bracelets
- Pens
- Badge clips

ACCEPTED
with COMMENTS
In EPA Letter Dated:
APR 21 2009

Under the Federal [illegible] Code, [illegible] Act as [illegible] No. 82012-3

- Name tags
- Patient gown snaps
- Window sills, pulls and locks
- Electrical wallplates

Community Facilities (including various public and commercial buildings)

- Shopping cart handles, child seats, handrails
- Cash registers: housing, keypads
- ATM machines: keys, housing
- Gym/Health club lockers, locker handles, locker shelving, trainers' tables,
- Ice and water dispensers (outer surfaces without water contact)
- Elevator: handrail, control panel, buttons, interior walls, floor tiles, exterior call button plate
- Paper towel dispensers. Housing itself, (turn) handle, (push) handle
- Soap holder
- Soap dispenser (wall mounted): push bar and dispenser itself
- Soap dispenser (sitting on counter): dispenser housing itself, push mechanism
- Toilet paper dispenser (housing)
- Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)
- Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)
- Light switches, switch plates
- Lids of laundry hampers, trash canisters, and other containers
- Magazine rack
- Signage
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Bracelets
- Badge clips
- Name tags
- Vending machines (non-food contact only)
- Window sills
- Electrical wallplates
- Clip boards
- Office supplies: paper clips, staplers, tape dispensers

Residential Buildings (including homes, apartments, apartment buildings and other residences)

- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Bedrails, footboards
- Handrails

- Stair rails
- Door push plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Paper towel holders, facial tissue holders, toilet paper holders
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Towel bars
- Showerheads
- Countertops and tabletops
- Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Light switches, switch plates
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- Floor tiles
- Ceiling tiles (non-porous)
- Wall tiles
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise equipment, handles, bars
- Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)
- Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)
- Television control knobs and buttons
- Lids of laundry hampers, trash canisters, and other containers
- [redacted]
- Closet rods and hangers
- Television remote
- [redacted]
- [redacted]
- Soap holder
- Magazine rack
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Window sills
- Electrical wallplates
- [redacted]
- Office supplies: paper clips, staplers, tape dispensers
- Monitor (television, computer, etc.) housing

ACCEPTED
with COMMENTS
In EPA Letter Dated:
APR 21 2009
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the registration of Reg. No. 82012-3

Mass Transit Facilities

- Handrails
- Stair rails, tubular railing, and supports; elbows and brackets
- Door push plates, kick plates
- Door handles, door knobs (outer touch surfaces)
- Grab bars and handles
- Tiles: wall, floor, ceiling (non-porous)
- Chairs and benches: rails, backs, legs, seats
- Window sills, pulls, and handles
- Signage
- Vending machines (non-food contact only)

Other

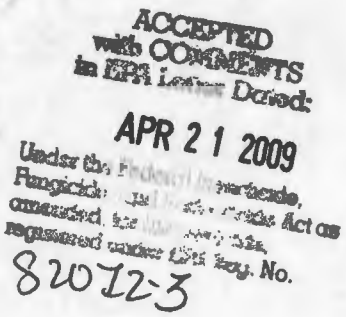
- Play area equipment (indoor only): bars, handles, chains, push plates, handrails, stair rails and risers, wheels, knobs, flooring
- Chapel pews
- Eye glass frames and protective eye wear
- Pens
- Combs
- Ashtrays

STORAGE AND DISPOSAL

Antimicrobial Copper Alloys should be disposed in a responsible manner, including recycling.

WARRANTY STATEMENT

If used as intended, Antimicrobial Copper Alloys are wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.



Sublabel II: Hang Tag Label

FRONT

Made from

Antimicrobial Copper Alloys Group III

Active Ingredient:

Copper	82.6%
Other	17.4%
Total	100.0%

See Back Panel for Directions for Use

ACCEPTED
with COMMENTS
In EPA Letter Dated:

APR 21 2009

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 82012-3

BACK

ANTIMICROBIAL COPPER ALLOYS GROUP III

Laboratory testing has shown that when cleaned regularly:

- This surface continuously reduces bacteria* contamination, achieving 99.9% reduction within 2 hours of exposure.
- This surface kills greater than 99.9% of Gram-negative and Gram-positive bacteria* within 2 hours of exposure.
- This surface delivers continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within 2 hours.
- This surface kills greater than 99.9% of bacteria* within two hours and continues to kill 99% of bacteria* even after repeated contaminations.
- This surface helps inhibit the buildup and growth of bacteria* within 2 hours of exposure between routine cleaning and sanitizing steps.

* Testing demonstrates effective antibacterial activity against *Staphylococcus aureus*, *Enterobacter aerogenes*, Methicillin-Resistant *Staphylococcus aureus* (MRSA), *Escherichia coli* O157:H7, and *Pseudomonas aeruginosa*.

The use of this product is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces. This surface has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Proper Care and Use. The use of this product does not replace standard infection control procedures and good hygienic practices. This product must be cleaned and sanitized according to standard practice. Healthcare facilities must maintain the product in accordance with infection control guidelines; users must continue to follow all current infection control practices, including those practices related to disinfection of environmental surfaces.

This surface may be subject to recontamination and the level of active bacteria at any particular time will depend on the frequency and timing of recontamination and cleanliness of the surface (among other factors). In order for this product to have proper antimicrobial effect, the product must be cleaned and maintained according to the directions included on this label.

This product must not be waxed, painted, lacquered, varnished, or otherwise coated.

Routine cleaning to remove dirt and filth is necessary for good sanitation and to assure the effective antibacterial performance of this surface. Cleaning agents typically used for traditional touching surfaces are permissible; the appropriate cleaning agent depends on the type of soiling and the measure of sanitization required. Normal tarnishing or wear of Antimicrobial Copper Alloy surfaces will not impair the antibacterial effectiveness of the product.

This product can not be used for any direct food contact or food packaging uses.

Surfaces that may be exposed to outdoor environmental conditions (e.g., handrails, shopping carts, child seats and ATM machines) are not representative of indoor laboratory test conditions, and therefore, may impart reduced efficacy if not cleaned when visibly soiled.

STORAGE AND DISPOSAL

Antimicrobial Copper Alloys Group III should be disposed in a responsible manner, including recycling.

WARRANTY STATEMENT

If used as intended, Antimicrobial Copper Alloys are wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.

EPA Reg. No. 82012-3 EPA Est. No. 82012-NY-001

Manufactured by: Copper Development Association, 260 Madison Ave., NY, NY 10016-2401

Antimicrobial Copper Alloys may be used in hospitals, other healthcare facilities, and various public, commercial, and residential buildings for the non-food contact surfaces listed below.

Surfaces that may be exposed to outdoor environmental conditions (*e.g.,* handrails, shopping carts, child seats and ATM machines) are not representative of indoor laboratory test conditions, and therefore, may impart reduced efficacy if not cleaned when visibly soiled.

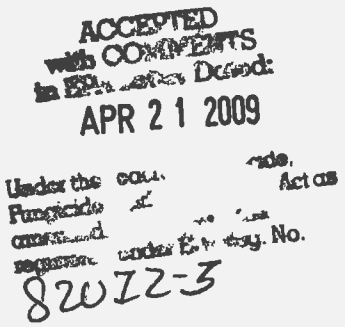
Healthcare Facilities

- Bedrails, footboards
- Over-bed tables
- Bed-side tables in hospitals, extended care facilities, senior housing etc. (knobs, pulls, handles; surfaces)
- Handrails, (corridor/hallways) (Senior housing), automatic door push plates
- Stair rails, handrails, tubular railing, and supports, rail fittings T's, elbows and brackets
- Bedrails, assistance rails,
- Toilet safety rails
- Carts
  - Hospital carts (table surfaces, handles, legs)
  - Computer carts
  - Record carts
  - Phlebotomy carts
  - Other Carts (tables/surfaces, shelving, railings, handles, pulls)
- Equipment carts (horizontal surfaces, frames, handles)
- Door push plates, kick plates, mop plates, stretcher plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Water fountains: bubbler head, drain strainer, handle
- Alcohol sanitizer dispenser, handle
- Paper towel holders, facial tissue holders, toilet paper holders
- Air hand dryer, controls and push buttons on air hand dryers
- Hydrotherapy tanks (whirlpool tanks): shells, covers, headrests, drain fittings (outer surfaces without water contact)
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Panic bars on emergency room doors
- Towel bars
- Showerheads
- Countertops and tabletops (non-food use only)
- Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Closures
- Vertical locking arms
- Vertical cover guards
- Protection bars
- Light switches, switch plates
- Visitor chairs: armrests, metal frames
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Floor tiles
- Ceiling tiles (non-porous)
- Wall tiles
- Instrument handles

  Medical equipment knobs, pulls and handles for:

  - Drug delivery systems
  - Monitoring systems
  - Hospital beds
  - Office equipment
  - Operating room equipment
  - Stands and fixtures

  Types of knobs: *e.g.*, Prong, fluted, knurled, push/pull, T-handle, tapered, and ball knobs
- Intravenous (IV) poles, bases, hangers, clips
- Trays (instruments, non-food contact)
- Pans (bed)
- Walkers, wheelchair handles, and tubular components
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise and rehabilitation equipment, handles, bars



- Physical therapy equipment: physical therapy tables, treatment chairs and portable taping tables
- Chairs (shower chairs, patient chairs, visitor chairs): rails, backs, legs, seats
- Lighting products: X-ray illuminators, operating rooms, patient examination rooms, surgical suites, and reading lamps for hospital rooms and assisted living facilities etc. Components can include bases, arms, housings, handles, hinges)
- Headwall systems: the unit themselves, outlet covers, knobs and dials, lighting units (lamp housings and adjustable arms), CRT monitors with rotating knobs and levers and adjustments. Baskets, monitor housings, knobs, baskets, tables, IV poles
- Critical care cart: Table top, drawer, drawer pull, lock, copper wire baskets for storage of equipment and charts.
- Bedside lavatory: sink, faucet, handles, drawer pulls, toilet seat, toilet seat cover, toilet handle, door and cabinet facings, counter tops
- Medical records: Chart holders, clipboards, filing systems
- Storage Shelving: wire shelving etc. for medical supplies
- Grab handles on privacy curtains
- Lids of laundry hampers, trash canisters, and other containers
- [redacted]
- Closet rods and hangers
- Television controls: knobs, buttons, remote
- Monitor (television, computer, etc.) housing
- [redacted]
- [redacted]
- Soap holder
- Magazine rack
- Signage
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Bracelets
- Pens
- Badge clips
- Name tags
- Patient gown snaps
- Window sills, pulls and locks
- Electrical wallplates

ACCEPTED
with COMMENTS
In EPA Letter Dated:
APR 21 2009
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the pesticide registered under EPA Reg. No. 82012-3

Community Facilities (including various public and commercial buildings)

- Shopping cart handles, child seats, handrails
- Cash registers: housing, keypads
- ATM machines: keys, housing
- Gym/Health club lockers, locker handles, locker shelving, trainers' tables,
- Ice and water dispensers (outer surfaces without water contact)
- Elevator: handrail, control panel, buttons, interior walls, floor tiles, exterior call button plate
- Paper towel dispensers. Housing itself, (turn) handle, (push) handle
- Soap holder
- Soap dispenser (wall mounted): push bar and dispenser itself
- Soap dispenser (sitting on counter): dispenser housing itself, push mechanism
- Toilet paper dispenser (housing)
- Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)
- Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)
- Light switches, switch plates
- Lids of laundry hampers, trash canisters, and other containers
- Magazine rack
- Signage
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Bracelets
- Badge clips
- Name tags
- Vending machines (non-food contact only)
- Window sills
- Electrical wallplates
- Clip boards
- Office supplies: paper clips, staplers, tape dispensers

Residential Buildings (including homes, apartments, apartment buildings and other residences)

- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Bedrails, footboards
- Handrails
- Stair rails
- Door push plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Paper towel holders, facial tissue holders, toilet paper holders
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Towel bars
- Showerheads
- Countertops and tabletops
- Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Light switches, switch plates
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- Floor tiles
- Ceiling tiles (non-porous)
- Wall tiles
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise equipment, handles, bars
- Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)
- Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)
- Television control knobs and buttons
- Lids of laundry hampers, trash canisters, and other containers
- [redacted]
- Closet rods and hangers
- Television remote
- [redacted]
- [redacted]
- Soap holder
- Magazine rack
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Window sills
- Electrical wallplates
- [redacted]
- Bowl stands
- Office supplies: paper clips, staplers, tape dispensers
- Monitor (television, computer, etc.) housing

ACCEPTED
with COMMENTS
In EPA Letter Dated:
APR 21 2009

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the registration under Reg. No. 82012-3

Mass Transit Facilities

- Handrails
- Stair rails, tubular railing, and supports; elbows and brackets
- Door push plates, kick plates
- Door handles, door knobs (outer touch surfaces)
- Grab bars and handles
- Tiles: wall, floor, ceiling (non-porous)
- Chairs and benches: rails, backs, legs, seats
- Window sills, pulls, and handles
- Signage
- Vending machines (non-food contact only)

Other

- Play area equipment (indoor only): bars, handles, chains, push plates, handrails, stair rails and risers, wheels, knobs, flooring
- Chapel pews
- Eye glass frames and protective eye wear
- Pens
- Combs
- Ashtrays

Please read instructions on reverse before comp[illegible] form. Form Approved. [illegible]MB No. 2070-0060, Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [x] Amendment
- [ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
82012-3	Marshall Swindell	[x] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Antimicrobial Copper Alloys Group III	33	

5. Name and Address of Applicant *(Include ZIP Code)*

Copper Development Association Inc.
260 Madison Avenue
New York, NY 10016

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [x] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in repsonse to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This submission is a fast-track label amendment and not subject to PRIA. Please see the cover letter for details of the proposed label revisions.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistent Packeging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [x] Other (Specify) none
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[x] Label [ ] Container	NA- no container	[x]

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued [ ] Stenciled [x] Other Attached to Bill of Lading

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Heather R. Bjornson, Technology Sciences Group, Inc.	Regulatory Assistant	(202) 828-8945

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Heather R Bjornson	Regulatory Assistant to Copper Development Assoc. Inc.
4. Typed Name	**5. Date**
Heather R. Bjornson	February 4, 2009

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

TECHNOLOGY SCIENCES GROUP INC

WASHINGTON
1150 18th Street, N.W.
Suite 1000
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

SACRAMENTO
712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

CANADA
275 Slater Street
Suite 900
Ottawa, Ontario
K1P 5H9
Telephone 613 247-6285
Fax 613 236-3754

E-mail tsg@tsgusa.com
http://www.tsgusa.com

February 4, 2009

Marshall Swindell, Team 33
Office of Pesticide Programs
US Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Copper Development Association
Antimicrobial Copper Alloys Groups 1 through 5
EPA Reg. Nos. 82012-1 through 5
Fast-track label amendments

Dear Mr. Swindell:

On behalf of the Copper Development Association (CDA), Technology Sciences Group Inc submits the enclosed fast-track label amendments to:

- Eliminate the footnote under the ingredient statement on the current master label, which currently appears as follows:

Active Ingredient:	
Copper	96.2%#
Other	3.8%#

 # Nominal percentages for purpose of review and approval. Actual percentage of copper and other ingredients will be indicated on labels distributed with the product.

Total	100%

States have objected to including the actual percentage of copper on the Retail Label and would prefer that the Retail Label reflect the nominal concentration for the Group, consistent with the Master Label. The states believe that this approach will result in less confusion for state inspectors.

- In addition, as a result of discussions with California, we are seeking to make two minor modifications to the claims language. These changes are as follows:

(1) Delete the underlined text in the current claim, as follows: "Antimicrobial Copper Alloy surfaces deliver continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9%

TECHNOLOGY SCIENCES GROUP INC

WASHINGTON
1150 18th Street, N.W.
Suite 1000
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

of bacteria* within two hours *even after* repeated wet and dry abrasion and re-contamination."

(2) Delete the underlined text in the current claim, as follows: "When cleaned regularly, Antimicrobial Copper Alloys surfaces kill greater than 99.9% of bacteria* within two hours, and continue to kill more than 99% of bacteria* even after repeated contamination."

- Lastly, we are adding additional use sites to the label.

SACRAMENTO
712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

You will find the following:

1) Application Form,
2) One redline label version for Groups 1 -5, and
3) Three clean copies of the label for each group 1 through five.

If you have any questions, please contact me at 202-828-8945 or by e-mail, hbjornson@tsgusa.com.

Sincerely,

Heather R. Bjornson

Heather R. Bjornson
Regulatory Assistant, Copper Development Association

cc: D. Edwards, EPA
H. Michels, CDA
J. Green, Kelley, Drye, Collier, Shannon

CANADA
275 Slater Street
Suite 900
Ottawa, Ontario
K1P 5H9
Telephone 613 247-6285
Fax 613 236-3754

E-mail tsg@tsgusa.com
http://www.tsgusa.com

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 9, 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JOSEPH J. GREEN
COLLIER SHANNON SCOTT, PLLC
COPPER DEVELOPMENT ASSOCIATION (CDA)
3050 K STREET, N.W., SUITE 400
WASHINGTON, DC 20007-

PRODUCT NAME: ANTIMICROBIAL COPPER ALLOYS - GROUP III
COMPANY NAME: COPPER DEVELOPMENT ASSOCIATION (CDA)
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 82012-3
EPA RECEIPT DATE: 02/06/09

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

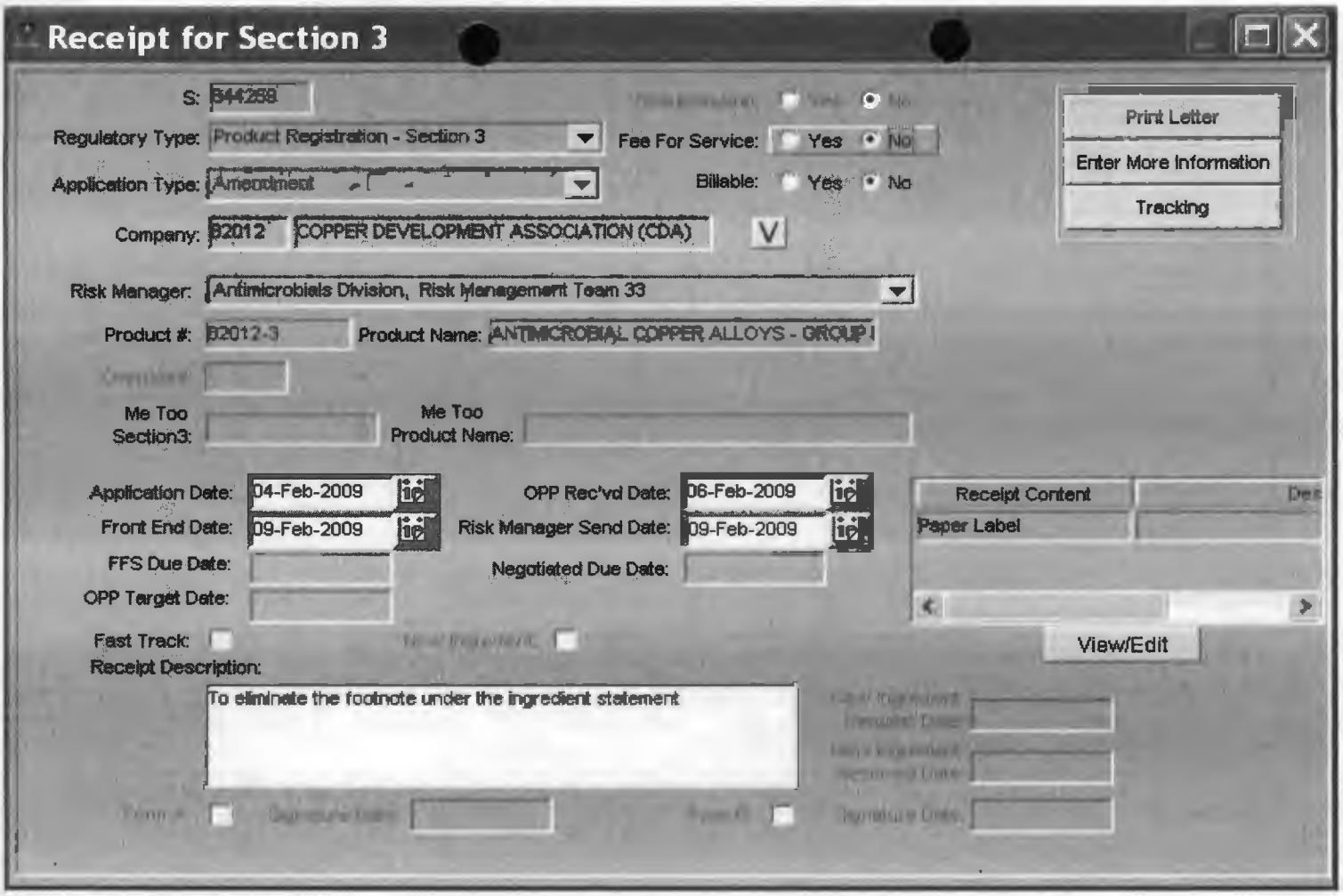
The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 33, at (703) 308-6341.

Sincerely,

P. L. Moore
Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division


Receipt for Section 3
S: 344259
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Amendment
Billable: Yes No
Company: 82012 COPPER DEVELOPMENT ASSOCIATION (CDA)
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 33
Product #: 82012-3
Product Name: ANTIMICROBIAL COPPER ALLOYS - GROUP I
Me Too Section3:
Me Too Product Name:
Application Date: 04-Feb-2009
OPP Rec'vd Date: 06-Feb-2009
Front End Date: 09-Feb-2009
Risk Manager Send Date: 09-Feb-2009
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Paper Label
Fast Track:
View/Edit
Receipt Description:
To eliminate the footnote under the ingredient statement

Fee for Service {844259G~

This package includes the following

- ○ New Registration
- • Amendment

Studies? Fee Waiver?

volpay % Reduction: ___

for Division

- • AD
- ○ BPPD
- ○ RD

Risk Mgr. 33

Receipt No.	S-	844259
EPA File Symbol/Reg. No.		82012-3
Pin-Punch Date:		2/6/2009

☒ This item is NOT subject to FFS action.

Action Code:

Requested: ____

Granted: ____

Amount Due: $ _____

Parent/Child Decisions:

▪ Inert Cleared for Intended Use ▪ Uncleared Inert in Product

Reviewer: Team 3 Date: 2/9/09

Remarks:

Material to be added to a Mini-Jacket
(in the case where an e-Jacket exists)

Reg. No. 82012-3

Send to SIG: check box ☑

This material is:

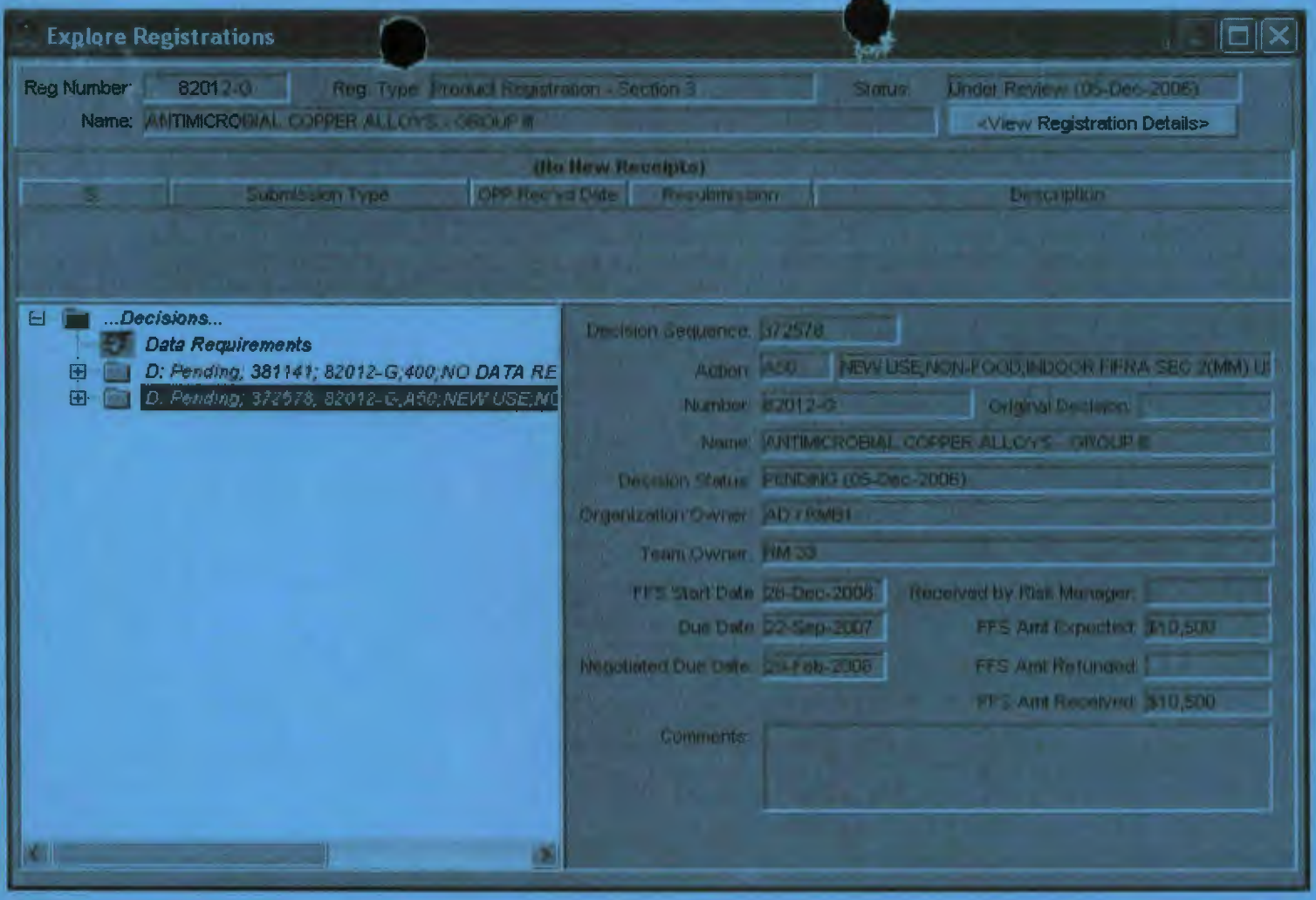
- € New stamped-accepted label
- € New CSF
- € Notification
- € Final Printed Label
- € Other: _____

Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: Karen Lee

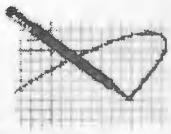
Phone: 308-6237 **Division:** AD

Date: 2/29/08


Explore Registrations
Reg Number: 82012-G
Reg. Type: Product Registration - Section 3
Status: Under Review (05-Dec-2006)
Name: ANTIMICROBIAL COPPER ALLOYS - GROUP II
<View Registration Details>
(No New Receipts)
S
Submission Type
OPP Recvd Date
Resubmission
Description
...Decisions...
Data Requirements
D: Pending; 381141; 82012-G;400;NO DATA RE
D: Pending; 372578; 82012-G;A50;NEW USE;NO
Decision Sequence: 372578
Action: A50
NEW USE,NON-FOOD,INDOOR FIFRA SEC 2(MM) U
Number: 82012-G
Original Decision:
Name: ANTIMICROBIAL COPPER ALLOYS - GROUP II
Decision Status: PENDING (05-Dec-2006)
Organization Owner: AD (OPP)
Team Owner: RM 33
FFS Start Date: 28-Dec-2006
Received by Risk Manager:
Due Date: 02-Sep-2007
FFS Amt Expected: $10,500
Negotiated Due Date: 24-Feb-2008
FFS Amt Refunded:
FFS Amt Received: $10,500
Comments:

2/29/08

Recommendation of Division Directors Negotiated Due Dates		
Decision#: 372579	**Registration#: 82012-G**	**Petition #:**
Fee Category: A50	**PRIA Decision Time Frame: 270days**	
Submitted by: Karen Leavy	**Branch: RMBI**	**Date: 02/13/2008**
Company: Copper Association, Inc.		
Original Due Date: 09/21/2007	**Proposed New Due Date: 02/29/08**	
Previous Negotiated Due Dates: 11/21/07,1/21/08, 02/15/08		
Is the "Fix" in-house? yes	**If not, date "Fix" expected:**	
Issue (describe in detail): Copper Association, Inc., submitted five applications for registration for copper alloy products. OGC has raised concerns regarding the labeling and claims given a 2 hour contact time. ASHES responded to an Agency inquiry on 2/7/08 and meetings with OGC/Bill Jordan are scheduled 2/20/08 to discuss the response and any remaining issues.		
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): The Agency has had several meetings with the Copper Association, Inc., and their regulatory consultants concerning the chemistry deficiencies and labeling issues. On September 18th, 2007, the Copper Association's regulatory consultants' requested a meeting to discuss the various deficiencies with their pending applications for registration.		
Rationale for Proposed Due Date: The 14-day time extension of (02/29/08) from the second time extension (02/15/2008) will allow time to discuss how to labeling and other issues raised by OGC concerning the pending copper alloy applications for registration. AD recommends that a 14-day time extension of be granted.		
Other Comments/Deficiency Type: **Product Chemistry: _X_ Acute Tox: __ Efficacy: _X_ Labeling: X Other: _X_**		
"75 Day" Letter appropriate? _X_ Yes _____No Why Not?		
Registrant notified that this is the last negotiation? _X_Yes _____No Why Not? This is the first re-negotiation.		
Approve: ✓	**Disapprove:**	
If disapproved, action to be taken:		
OD or DOD Signature:	**Date:** 2-14-08	



Karen Leavy/DC/USEPA/US
02/13/2008 02:37 PM

To Dennis Edwards/DC/USEPA/US@EPA, Marshall Swindell/DC/USEPA/US@EPA
cc
bcc
Subject Fw: Time Extension request - Antimicrobial Copper Alloys

Gentlemen,

I know Joe Green forwarded this message to your e-mails but here is the formal time extension request for the pending copper alloy products. Hopefully, you received my e-mail containing the revised copper alloy time extensions. They need to go up for signature as soon as possible.

KML

-----Forwarded by Karen Leavy/DC/USEPA/US on 02/13/2008 02:37PM -----

To: Karen Leavy/DC/USEPA/US@EPA
From: "Green, Joseph J." <JGreen@KelleyDrye.com>
Date: 02/13/2008 12:41PM
cc: Dennis Edwards/DC/USEPA/US@EPA, Marshall Swindell/DC/USEPA/US@EPA
Subject: Time Extension request - Antimicrobial Copper Alloys

Karen - On behalf of the Copper Development Association, I would like to
request extension of the current PRIA due date for review of the five
pending registration applications for Antimicrobial Copper Alloys. As
discussed with Dennis, the new PRIA deadline would be February 29, 2008.

Please let me know if you need anything else.

Thanks
Joe

Joseph J. Green
Kelley Drye Collier Shannon
3050 K Street, N.W.
Washington, D.C. 20007
202.342.8849
Fax: 202.342.8451
www.kelleydrye.com

please be aware that any other use, printing, copying, disclosure or dissemination of this communication may be subject to legal restriction or sanction. If you think that you have received this E-mail message in error, please reply to the sender.

This E-mail message and any attachments have been scanned for viruses and are believed to be free of any virus or other defect that might affect any computer system into which it is received and opened. However, it is the responsibility of the recipient to ensure that it is virus free and no responsibility is accepted by Kelley Drye & Warren LLP for any loss or damage arising in any way from its use.

Recommendation of Division Directors Negotiated Due Dates		
Decision#: 372578	Registration#: 82012-G	Petition #:
Fee Category: A50	PRIA Decision Time Frame: 270days	
Submitted by: Karen Leavy	Branch: RMBI	Date: 01/14/08
Company: Copper Association, Inc.		
Original Due Date: 09/21/2007	Proposed New Due Date: 02/15/08	
Previous Negotiated Due Dates: 01/21/2008		
Is the "Fix" in-house? Company response is in-house. Still waiting on ASHES to respond to EPA e-mail.	If not, date "Fix" expected:	
Issue (describe in detail): Copper Association, Inc., submitted five applications for registration for copper alloy products which included chemistry data, efficacy data, acute toxicity data, administrative forms, and proposed product labeling. Upon review of the efficacy data, some of the claims that appear on the proposed labeling must be revised and/or deleted. In addition, OGC has raised concerns about the appropriate efficacy contact time for the finish copper products. In addition, revised product labeling must be submitted.		
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): The Agency has had several meetings with the Copper Association, Inc., and their regulatory consultants concerning the chemistry deficiencies and labeling issues. On September 18th, 2007, the Copper Association's regulatory consultants' requested a meeting to discuss the various deficiencies with their pending applications for registration. On November 20th, 2007, a 75 letter was faxed to the regulatory consultants outlining the various deficiencies. On January 14th, 2008, the regulatory consultants requested a 25- day time extension (02/15/2008) from the re-negotiated due date (01/21/2008) in order to have a meeting with the Agency to discuss how to satisfy the various deficiencies. On January 14th, 2008, the regulatory consultants requested a 25-day time extension (02/15/2008) from the second time extension of (01/21/2008) in order to meet with the Antimicrobial Division to discuss the various labeling and science issues raised by OGC concerning the pending copper alloy applications for registration.		
Rationale for Proposed Due Date: The 25-day time extension of (02/15/08) from the second time extension (01/21/2008) will allow the Copper Association, Inc., enough time to meet with the Agency to discuss how to satisfy the labeling and science issues raised by OGC concerning the pending copper alloy applications for registration. AD recommends that a 25-day time extension of (02/15/2008) from the second time extension (01/21/2008) be granted.		
Other Comments/Deficiency Type: Product Chemistry: __ Acute Tox: __ Efficacy: __ Labeling: X Other: X		

"75 Day" Letter appropriate? ___X__Yes _____No Why Not?	
Registrant notified that this is the last negotiation? _____Yes __X___No Why Not?	
Approve: √	**Disapprove:**
If disapproved, action to be taken:	
OD or DOD Signature: Mark Mendl	**Date:** 1-17-08

Karen Leavy/DC/USEPA/US
01/14/2008 03:40 PM

To Dennis Edwards/DC/USEPA/US@EPA, Marshall Swindell/DC/USEPA/US@EPA
cc
bcc
Subject Fw: Time Extension request - Antimicrobial Copper Alloys

Dennis,

Here is the time extension request(s) for the pending copper alloy products.

KML

----- Forwarded by Karen Leavy/DC/USEPA/US on 01/14/2008 03:39 PM -----

"Green, Joseph J." <JGreen@KelleyDrye.com>
01/14/2008 11:19 AM

To Karen Leavy/DC/USEPA/US@EPA
cc Dennis Edwards/DC/USEPA/US@EPA, Marshall Swindell/DC/USEPA/US@EPA
Subject RE: Time Extension request - Antimicrobial Copper Alloys

Karen - On behalf of the Copper Development Association, I would like to request a further extension of the PRIA due date for review of the five pending registration applications for Antimicrobial Copper Alloys. As discussed with Dennis, the new PRIA deadline would be February 15, 2008.

Please let me know if you need anything else.

Thanks
Joe

Joseph J. Green
Kelley Drye Collier Shannon
3050 K Street, N.W.
Washington, D.C. 20007
202.342.8849
Fax: 202.342.8451
www.kelleydrye.com

-----Original Message-----
From: Leavy.Karen@epamail.epa.gov [mailto:Leavy.Karen@epamail.epa.gov]
Sent: Monday, January 14, 2008 10:46 AM
To: Green, Joseph J.
Cc: Edwards.Dennis@epamail.epa.gov; Swindell.Marshall@epamail.epa.gov
Subject: Time Extension request

Joe,

Is the Copper Association close to finalizing their time extension request for the pending copper alloy products? I really need that time

extension sometime today.

KML

Recommendation of Division Directors Negotiated Due Dates		
Decision#: 372578	Registration#: 82012-EG	Petition #:
Fee Category: A50	PRIA Decision Time Frame: 270days	
Submitted by: Karen Leavy	Branch: RMBI	Date: 11/20/07
Company: Copper Association, Inc.		
Original Due Date: 09/21/2007	Proposed New Due Date: 01/21/2008	
Previous Negotiated Due Dates: 11/21/2007		
Is the "Fix" in-house? yes	If not, date "Fix" expected:	

Issue (describe in detail): Copper Association, Inc., submitted five applications for registration for copper alloy products which included chemistry data, efficacy data, acute toxicity data, administrative forms, and proposed product labeling. Upon review of the efficacy data, some of the claims that appear on the proposed labeling must be revised and/or deleted. In addition, OGC has raised concerns about the appropriate efficacy contact time for the finish copper products. In addition, revised product labeling must be submitted.

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): The Agency has had several meetings with the Copper Association, Inc., and their regulatory consultants concerning the chemistry deficiencies and labeling issues. On September 18th, 2007, the Copper Association's regulatory consultants' requested a meeting to discuss the various deficiencies with their pending applications for registration. On September 20th, 2007, a 75 letter was faxed to the regulatory consultants outlining the various deficiencies. On September 20th, 2007, the regulatory consultants requested a 60 day time extension (11/21/2007) from the original due date (09/21/2007) in order to have a meeting with the Agency to discuss how to satisfy the various deficiencies. On November 20th, 2007, the regulatory consultants requested a second 60 day time extension (01/21/2008) from the first time extension of (11/21/2007) in order to meet with the Antimicrobial Division to discuss the various labeling and science issues raised by OGC concerning the pending copper alloy applications for registration.

Rationale for Proposed Due Date: The second 60 day time extension of (01/21/08) from the first time extension (11/21/2007) will allow the Copper Association, Inc., enough time to meet with the Agency to discuss how to satisfy the labeling and science issues raised by OGC concerning the pending copper alloy applications for registration. AD recommends that a second 60 -day time extension of (01/21/2008) from the first time extension (11/21/2007) be granted.

Other Comments/Deficiency Type:

Product Chemistry: _X_ **Acute Tox:** __ **Efficacy:** _X_ **Labeling:** X **Other:** _X_

"75 Day" Letter appropriate? __X__ **Yes** _____ **No Why Not?**

Registrant notified that this is the last negotiation? _____Yes __X___No Why Not? This is the first re-negotiation.	
Approve: ✓	**Disapprove:**
If disapproved, action to be taken:	
OD or DOD Signature: Matt Mcull	**Date:** 11-21-07

Karen Leavy/DC/USEPA/US
11/20/2007 12:48 PM

To Dennis Edwards/DC/USEPA/US@EPA
cc
bcc
Subject Fw: Antimicrobial Copper Alloys Groups 1 - 5: Registration and PRIA Due Date (EPA file Symbols 82012-R through L); PRIA EXTENSION REQUEST

Dennis,

Here is the time extension requests for the copper alloy products.

KML

----- Forwarded by Karen Leavy/DC/USEPA/US on 11/20/2007 12:47 PM -----

"Green, Joseph J." <JGreen@KelleyDrye.com>
11/20/2007 12:00 PM

To Karen Leavy/DC/USEPA/US@EPA, Dennis Edwards/DC/USEPA/US@EPA
cc Marshall Swindell/DC/USEPA/US@EPA, "Michels, Harold" <hmichels@cda.copper.org>
Subject Antimicrobial Copper Alloys Groups 1 - 5: Registration and PRIA Due Date (EPA file Symbols 82012-R through L); PRIA EXTENSION REQUEST

Dennis and Karen -

Based on our discussions, we agree that it makes sense to meet next week and have a follow up meeting in early December to work through the identified issues. We also agree that it is appropriate to extend the PRIA deadline to ensure that an appropriate registration decision can be made.

Accordingly, on behalf of the Copper Development Association, we hereby request an additional 60-day extension to the previously revised PRIA deadline for the 5 registration applications for Antimicrobial Copper Alloys Groups 1 - 5 (EPA File Symbols 82012-R through L). The current PRIA deadline is November 21, 2007. With the extension, the new PRIA deadline will be **January 21, 2008**.

Please let me know if you need anything else.

We look forward to our meeting next week.

Regards,

Joe

Joseph J. Green
Kelley Drye Collier Shannon
3050 K Street, N.W.
Washington, D.C. 20007
202.342.8849
Fax: 202.342.8451
www.kelleydrye.com

Recommendation of Division Directors Negotiated Due Dates		
Decision#: 372578	**Registration#:** 82012-G	**Petition #:**
Fee Category: A50	**PRIA Decision Time Frame:** 270 days	
Submitted by: Karen Leavy	**Branch:** RMBI	**Date:** 9/20/2007
Company: Copper Association, Inc.		
Original Due Date: 09/22/2007	**Proposed New Due Date:** 11/21/2007	
Previous Negotiated Due Dates: N/A		
Is the "Fix" in-house? Yes	**If not, date "Fix" expected:**	

Issue (describe in detail): Copper Association, Inc., submitted five applications for registration for copper alloy products which included chemistry data, acute tox. data, efficacy data, administrative forms, and proposed product labeling. Upon review of the efficacy data, some of the claims that appear on the proposed labeling must be revised and/or deleted. In addition, OGC has raised concerns about the appropriate efficacy contact time for the finished copper products. In addition, revised product labeling must be submitted to the Agency for our review.

Summary of Deficiency Type(s): Not Submitted (N) Deficiencies (D)
Product Chemistry: _D__ **Acute Tox:** ___ **Efficacy:** __D__ **Labeling:** __D__ **Other (describe):** D

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): The Agency has had several meetings with the Copper Association, Inc., and their regulatory consultants concerning the chemistry deficiencies and labeling issues. On September 18th, 2007, the Copper Association's regulatory consultants' regulatory consultants' requested a meeting to discuss the various deficiencies with their deficiencies. On September 20th, 2007, a 75 day letter was faxed to the regulatory consultants outlining the various deficiencies. On September 20th, 2007, the regulatory consultants requested a 60 day time extension (11/22/2007) from the original due date (09/22/2007) in order to have a meeting with the Agency to discuss how to satisfy the various deficiencies. In addition, the time extension will enable the Agency enough time to discuss the policy and science issues raised by OGC concerning the pending copper alloy applications for registration.

"75 Day" Letter sent? 09/20/2007(Date sent)Yes ____No and reason for none?

Rationale for Proposed Due Date: The 60-day time extension of (11/22/2007) will allow the Copper Association, Inc., to meet with the Agency to discuss how to satisfy the outstanding data requirements. In addition, the Agency will have enough time to address the policy and science issues raised by OGC. AD recommends that a 60-day time extension of (11/22/2007) from the original due date of (09/22/2007) be granted.

Registrant notified that this is the last negotiation? ____Yes X Not Applicable

Approve: ✓	**Disapprove:**

If disapproved, action to be taken:

OD or DOD Signature:	**Date:** 9-21-07

Karen Leavy/DC/USEPA/US
09/20/2007 01:01 PM

To Dennis Edwards/DC/USEPA/US@EPA, Marshall Swindell/DC/USEPA/US@EPA
cc
bcc
Subject Fw: Antimicrobial Copper Alloys Groups 1 - 5: Registration and PRIA Due Date (EPA file Symbols 82012-R through L); PRIA EXTENSION REQUEST - CORRECTION

Gentlemen,

Here is the time extension request from Joe Green.

KML
----- Forwarded by Karen Leavy/DC/USEPA/US on 09/20/2007 01:01 PM -----

"Green, Joseph J." <JGreen@KelleyDrye.com>
09/20/2007 12:47 PM

To Dennis Edwards/DC/USEPA/US@EPA
cc Marshall Swindell/DC/USEPA/US@EPA, Karen Leavy/DC/USEPA/US@EPA, "Michels, Harold" <hmichels@cda.copper.org>, "Robert Stewart" <RStewart@TSGUSA.COM>
Subject RE: Antimicrobial Copper Alloys Groups 1 - 5: Registration and PRIA Due Date (EPA file Symbols 82012-R through L); PRIA EXTENSION REQUEST - CORRECTION

All - I understand that due to how things work with EPA's system that the new PRIA due date will be Nov. 21, 2007. This e-mail confirms our request for an extension until that date for the above-captioned products. I have modified our extension request below to reflect this.

Regards,
Joe

Joseph J. Green
Kelley Drye Collier Shannon
3050 K Street, N.W.
Washington, D.C. 20007
202.342.8849
Fax: 202.342.8451
www.kelleydrye.com

-----Original Message-----
From: Green, Joseph J.
Sent: Thursday, September 20, 2007 11:03 AM
To: 'Edwards.Dennis@epamail.epa.gov'
Cc: 'Swindell.Marshall@epamail.epa.gov'; 'Leavy.Karen@epamail.epa.gov'; 'Michels, Harold'; 'Robert Stewart'
Subject: RE: Antimicrobial Copper Alloys Groups 1 - 5: Registration and PRIA Due Date (EPA file Symbols 82012-R through L); PRIA EXTENSION REQUEST

Dennis - thank you for the response. We agree that it makes sense to meet in early October to work through the identified issues and to

conduct the efficacy studies to ensure that the design of the studies was adequate and vigorous enough to support the proposed label claim. This will take some time in that the efficacy group must fit this re-evaluation in their normal work load. In addition, they have raised a policy question regarding the contact time and whether the Agency should register products making public health claims requiring a lengthy contact time. Some of the proposed uses involve items that are used in critical care or potentially areas that need to be treated. They point out there is unlikely to be a 2 hour delay between product user exposures to the copper surface. Many of the use sites will have continual use. There were concerns raised that the product (i.e. door knob) would not contain a label once placed into use. So how would anyone be expected to follow label directions critical to achieving the efficacy of the product, such as do not paint, lacquer or wax the surface. Additionally, the surfaces must be clear of soil to be effective. How will the purchaser/user be reminded without a label. A meeting with our OGC is probably needed to discuss these concerns.

Please let me know given the concerns that you need to address what time extension the Association will be requesting.

Dennis Edwards
Antimicrobials Division
703-308-8087

"Green, Joseph J." <JGreen@KelleyDrye.com>

09/18/2007 03:25 PM

To: Dennis Edwards/DC/USEPA/US@EPA

cc: Marshall Swindell/DC/USEPA/US@EPA, "Michels, Harold" <hmichels@cda.copper.org>, "Robert Stewart" <RStewart@TSGUSA.COM>, Karen Leavy/DC/USEPA/US@EPA

Subject: Antimicrobial Copper Alloys Groups 1 - 5: Registration and PRIA Due Date (EPA file Symbols 82012-R through L); Meeting Request

Dear Dennis --

Following up on our call yesterday regarding the Copper Alloys registrations, we wanted to address the issues you raised and propose

Kelley Drye Collier Shannon
3050 K Street, N.W.
Washington, D.C. 20007
202.342.8849
Fax: 202.342.8451
www.kelleydrye.com

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 10 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Robert Stewart
Regulatory Consultant for,
Copper Development Association (CDA)
3050 K Street, N.W., Suite 400
Washnigton, D.C. 20007

Mail to: Attn: Robert Stewart
Technology Sciences Group, Inc.
1150 18th Street, N.W., Ste. 1000
Washington, D.C. 20036-1795

Subject: Antimicrobial Copper Alloys-Group I
EPA File Symbol 82012-R
Antimicrobial Copper Alloys-Group II
EPA File Symbol 82012-E
Antimicrobial Copper Alloys-Group III
EPA File Symbol 82012-G
Antimicrobial Copper Alloy-Group IV
EPA File Symbol 82012-U
Antimicrobial Copper Alloys-Group V
EPA File Symbol 82012-L
Your Application Dated December 1st, 2006
EPA Received Date December 4th, 2006

Our records indicate the decision period for EPA to make a determination regarding the above referenced application ends on September 21st, 2007, as pursurant to the Pesticide Registration Improvement Act(PRIA). The Agency has reviewed your application and determined the action to be deficient for the following reasons:

Upon a cursory review of the cover letter and acute toxicity data waivers submitted in support of this application for registration, the Agency has determined that a number of critical issues must be addressed before initiating a full science review.

Provide an explanation concerning the broad percentages of the components that appear on the Confidential Statement of Formula.

The proposed labeling specifies the manufactured product(s) which the Agency considers indirect food-contact sites: e.g., food carts, sinks, countertops, kitchen surfaces, ice/ water dispensers. For such sites, the Agency will need to perform a dietary exposure/risk assessments due to the presence of trace toxic metals in the alloy compositions. Please note that if food contact sites are intended for registration, then it appears that a tolerance or tolerance exemption is in order to support such uses (e.g., table tops, counter tops).

Otherwise, these sites should be removed from the label be removed from the label or further qualified. This can be further discussed during a meeting.

Provide information as to how the manufacturing site "establishment numbers" will be determined.

Provide any information concerning the use of copper alloys in various use sites that may involve review from other federal Agencies such as Consumer Product Safety Commission, and Federal Drug and Food Administration in order to aid in the registration process.

Since some of the ingredients that appear on the Confidential Statement of Formula may be considered toxic substances under the Toxic Substances Control Act (TSCA), provide additional information pertaining to the use of these ingredients in the formulation(s).

The proposed product labeling states that contact surfaces must be regularly cleaned or sanitized, in order to assure antibacterial performance. However, it appears to be an unusual circumstance where the bacteriostatic surface must be cleaned and/or sanitized in order to perform as claimed. The Agency believes that such regular cleaning, or sanitizing, may provide for increased release of alloy components. Provide to the Agency information/evidence that an increase in the of alloy components does not occur with regular cleaning.

Please note that other data is required to support registration of the proposed use patterns (e.g., human exposure, residue chemistry). Data waivers for these data requirements may also be needed to satisfy any outstanding data requirements.

A meeting with the Copper Development Association and the Agency is warranted in order to get a clearer understanding of the submitted applications for registration.

These deficiencies must be corrected before the Agency can proceed further with this application.

You have the following three options.

1. Resolve the issue(s). You may resolve the issue(s) identified in this letter by submitting the information/data/studies within 10 business days or an explanation of why it will take longer to correct the deficiency or deficiencies. Please include your proposed re-negotiated PRIA due date at this time. If no other issues araise as a result of your response(s) to this letter, it is the Agency's explanation that resolution of the deficiencies will result in the granting of your application.

2. Withdraw your application. You may voluntarily withdraw your application and receive up to 90% of any monies paid under PRIA if this action is taken before day 60 of your PRIA start date. If you voluntarily withdraw your application after on the Agency website. You may view this at https://www.epa.gov./pesticides/fees/fee reduction.htm. Once you resubmit your application, it will subject to a new PRIA fee and schedule.

3. Do nothing. If you do not respond to this letter within 10 business days, or if you do not wish to re-negotiate the PRIA deadline, the Agency may issue a determination not to grant your application may require a new PRIA application and fee. Because this determination is not a denial under section 3(c)(6) of FIFRA and 40 CFR 152.118. The process includes publication of a notice of denial in the Federal Register and a possible public hearing.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

Marshall Swindell
Product Manager 33
Regulatory Manager Branch I
Antimicrobial Division(7510P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Dr. Robert R. Stewart, Ph.D.
Regulatory Consultant for,
Copper Development Association
1150 18th Street, N.W.
Suite 1000
Washington, D. C. 20036

SEP 20 2007

Subject: Antimicrobial Copper Alloys Groups 1
EPA File Symbol 82012-R
Antimicrobial Copper Alloys Groups 2
EPA File Symbol 82012-E
Antimicrobial Copper Alloys Groups 3
EPA File Symbol 82012-G
Antimicrobial Copper Alloys Groups 4
EPA File Symbol 82012-U
Antimicrobial Copper Alloys Groups 5
Your Application Dated June 7th, 2007
EPA Received Date June 21st, 2007

Our records indicate the decision period for EPA to make a determination regarding the above referenced application ends on September 21st, 2007, as pursurant to the Pesticide Registration Improvement Act(PRIA). The Agency has reviewed your application and determined the action to be deficient for the following reasons:

1. The Agency has determined that playground equipment must be removed from the product labeling because the efficacy tests performed do not adequately represent conditions the surfaces would be exposed to in an outdoor environment. In addition, all textiles such as uniforms, curtains, sheets, pillow cases, must be removed from the product labeling because these are considered porous surfaces for which efficacy has not been demonstrated.

2. The Agency has determined that shopping carts handles and child seats must be removed from the proposed label. These surfaces are extremely high-touch surfaces, unlikely to be cleaned every 24 hours. Furthermore, these surfaces are likely to be left outside for extended periods.

3. Surfaces that are high-touch surfaces with significant bioload and aren't practical to clean on a consistent basis (therefore efficacy may not be demonstrated if cleaning is not performed on a daily/routine basis). The surfaces listed below must be removed from your label. The rationale for removing these surfaces is based on efficacy data. Indication of daily cleaning is mandatory for high-touch surfaces that may undergo frequent re-colonization. These surfaces are:

Healthcare Facilities
Bedrails, footboards
Bedrails, assistance rails
Paper towel holders
Alcohol sanitizer dispenser handles
Showerheads
Visitor chairs, armrest, metal frames
Closures
Vertical locking arms
Vertial cover guards
Protection bars
Thermostat covers
Telephone handsets and surfaces(housings) keyboards
Ceiling tiles(request additional information, regarding types, often these are porous)
Walkers, wheelchair handles, and tubular components
Computer keyboards: keys, housing, keyboard
Medical records; chart holders, clipboards, filing systems
Storage shelving: wire shelving, etc. for medical supplies

Community Facilities
Cash registers: housing, keypads
ATM machines: keys, housing(must be indoor)
Gym/Health club lockers, locker handles locker shelving, trainers' table
Ice and water dispensers (outer surfaces without water contactO
Windows (crank), Locking mechanism, pull handles
Window treatments (cord pulls, Venetian blinds (wands, cord pulls)
Jalousie Windows (crank)
Casement (cranks, levers, hinges)
Single and double-hung windows (locks and pulls)

4. On page 5 of the proposed label(mid-way through the list of use surfaces), add non-food contact only in parenthesis next to "countertops and tabletops".

5. Revise the "Directions for Use" to include use directions for use for each item such as door knob, door kick plate, and other items listed on the proposed labeling. For example, a door knob will need installation directions which must be a part of the label. Each item needs to have a set of directions that will appear on the packaging in channels of trade.

6. The Agency has concerns over the use of [redacted] in these products, specifically as to whether these materials leach out. Additional data are needed in order for us to be able to assess the use of these materials. Therefore, the Agency requests that these inert ingredients be removed from the proposed formulations as well as the Confidential Statements of Formula until data to address these concerns are submitted. Submit new corrected CSFs for your five products.

7. Include a statement on your product labeling which prohibits the use of [redacted] in any copper alloy formulation for any of these registrations.

8. The "retail label" proposing the format "Manufactured by" and "Produced by" is not acceptable. There is nothing in our regulations that allows a product to mimic a supplemental registration without actually being a supplemental registration other than the product actually obtaining its own separate registration. 40 CFR 152.132 states that "The registrant may distribute or sell his registered product under another person's name and address instead of (or in addition to) his own. Such distribution and sale is termed "supplemental distribution" and the product is referred to as a "distributor product."

9. The proposed logo "Copper Shield" is not acceptable. This logo is similar to the caduceus, a medical seal of approval, and is considered an implied safety claim as well as an enhanced efficacy claim for the products.

10. Our toxicologist has granted a waiver of the six required acute toxicity studies.

Please note that additional labeling changes and/or information /data may be required to support registration of these products. Questions have arisen concerning the registrability of these products under the Federal Insecticide, Fungicide, and Rodenticide Act. The Antimicrobials Division consulting with our office of General Counsel and Enforcement Divisions to address these concerns.

Revised labeling and new CSF's for the proposed products must be submitted.

If these data requirements are not satisfied, then one (1) of the following three options below will apply.

These deficiencies must be corrected before the Agency can proceed further with this application.

You have the following three options.

1. Resolve the issue(s). You may resolve the issue(s) identified in this letter by submitting the information/data/studies within 10 business days or an explanation of why it will take longer to correct the deficiency or deficiencies. Please include your proposed re-negotiated PRIA due date at this time. If no other issues araise as a result of your response(s) to this letter, it is the Agency's explanation that resolution of the deficiencies will result in the granting of your application.

2. Withdraw your application. You may voluntarily withdraw your application and receive up to 90% of any monies paid under PRIA if this action is taken before day 60 of your PRIA start date. If you voluntarily withdraw your application after on the Agency website. You may view this at https://www.epa.gov./pesticides/fees/fee reduction.htm. Once you resubmit your application, it will subject to a new PRIA fee and schedule.

3. Do nothing. If you do not respond to this letter within 10 business days, or if you do not wish to re-negotiate the PRIA deadline, the Agency may issue a determination not to grant your application may require a new PRIA application and fee. Because this determination is not a denial under section 3(c)(6) of FIFRA and 40 CFR 152.118. The process includes publication of a notice of denial in the Federal Register and a possible public hearing.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

Marshall Swindell
Product Manager 33
Regulatory Manager Branch I
Antimicrobial Division(7510P)

DECISION PKG. NO. 381141 SUBM. DUE DATE 6/21/07

SUBMISSION BAR CODE # 812415 REVIEWER KL

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 82012-G PM 33 ACTION CODE A50

DESCRIPTOR Resubm **FQPA** **NFQPA**

[ ] CHILD RESISTANT PACKAGING: [ ] REQUIRED [ ] NOT REQUIRED

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL [ ] RESTRICTED USE

DATE ON APPLICATION	EPA RECEIVE DATE	PM RECEIVE DATE
6/7/07	6/21/07	6/21/07

METHOD OF SUPPORT

[ ] CITE-ALL [ ] SELECTIVE
[ ] NOT SUBMITTED [ ] N/A

FORMULATORS EXEMPTION

[ ] SUBMITTED [ ] NOT SUBMITTED
[ ] N/A

REVIEW(S) REQUESTED	DATA PACK #	DATE SENT	DUE DATE	DATE RETURNED
CHEMISTRY				
EFFICACY				
ACUTE TOX.				
RASSB TOX.				
ENVIRON. FATE				
FISH/WILDLIFE				
OTHER: :				

STATUS

RESPONSE CODE 1170 RESPONSE DATE 2/29/08

SCIENCE GROUP	DIVISION	BRANCH	SECTION	CSF Y/N	LABEL Y/N
CHEMISTRY	AD	EASSB	CTT		
EFFICACY	AD	EASSB	EET		

DATA PACKAGE BEAN SHEET

Date: 09-Jan-2008

Decision #: 381141

DP #: (348128)

NON PRIA

Parent DP#:

* * * Registration Information * * *

Registration: 82012-G - ANTIMICROBIAL COPPER ALLOYS - GROUP III

Company: 82012 - COPPER DEVELOPMENT ASSOCIATION (CDA)

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828

Risk Manager Reviewer: Karen Leavy KLEAVY

Sent Date: 21-Jun-2007 Calculated Due Date: ~~21-Jun-2007~~ 1/21/08 eff. Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (400) NO DATA REQUIRED;

Ingredients: 022501, Copper (metallic)(82.6%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 09-Jan-2008 Due Back:

DP Ingredient: 022501, Copper (metallic)

DP Title:

CSF Included: ○ Yes ● No Label Included: ○ Yes ● No Parent DP #:

	Assigned To	Date In	Date Out	
Organization:	AD / PSB			Last Possible Science Due Date: 03-Mar-2007
Team Name:	CTT			Science Due Date:
Reviewer Name:	Juan	1/9/08	1/10/08	Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

Printed on Page 2

* * * Data Package Instructions * * *

Review updated CSFS to remove metals.
Attn: Juan Negron

December 20, 2007

Dennis Edwards, Chief Regulatory Branch 1
Antimicrobials Division
Environmental Protection Agency
USEPA Headquarters
Ariel Rios Building
1200 Pennsylvania Avenue, N. W.
Mail Code: 7510P
Washington, DC 20460

Dear Mr. Edwards,

Thank you for contacting APIC regarding new product registration applications related to copper alloy products currently pending with the Antimicrobials Division in the Environmental Protection Agency's Office of Pesticides Program.

APIC is a nonprofit, multi-disciplinary, international organization, representing more than 11,000 infection control professionals (ICPs). APIC's mission is to improve health and promote safety by reducing risks of infection and other adverse outcomes in patients and health care workers.

In addition to the importance of APIC input as it relates to health care facilities, as you know many antimicrobial surface treatments or antimicrobial-containing composites which may initially be marketed to health care end up reaching the consumers too. This raises the issue of marketing claims which may be of concern to APIC members. APIC members appreciate the EPA's quick effort to counter marketing claims from some manufacturers a few years ago that alleged that antimicrobials incorporated into surfaces could prevent infection. (See attached "Excerpts from prior EPA guidance to consumers.)

APIC committee members were not aware of peer reviewed evidence documenting prevention of health care-associated infections (HAIs) related to the products pending registration. Further, the current media attention on pathogens such as MRSA will naturally stimulate emergence of "easy fixes" from manufacturers. Historically, these "quick fixes" rarely survive the peer review process in terms of supporting evidence and draw attention away from the harder, but more likely sustainable, solutions such as hygiene for hands and the environment.

There is a very good review of the topic of surface disinfection by Dr. Syed Sattar at the University of Ottawa, Canada, in the proceedings of Dr. Rutala's symposium on Disinfection, Sterilization and Antisepsis held during APIC 2006 and published by APIC earlier this year. Quotes from his presentation are particularly relevant to the discussion of copper alloy which has been tested for its efficacy against influenza virus. Dr. Sattar correctly points out that, "...pathogens such as HIV, HBV, HCV, SARS CoV, and also possibly avian influenza virus, require environmental surface disinfection to prevent and control their spread. With the possible exception of environmental surface disinfection to minimize the spread of HBV and HCV in kidney dialysis units, there is no evidence that environmental surfaces play a role in the spread of the above-mentioned viruses in healthcare or other settings...

...With regards to the nature of surfaces, the use of copper-based material instead of stainless steel has been shown to reduce rates of environmental survival of pathogens such as MRSA.... the adoption and wide-spread use of microbiocide-impregnated environmental surfaces be postponed awaiting availability of proper data on their long-term safety and effectiveness..." [Sattar S, Springthorpe VS. Disinfection of environmental surfaces to interrupt the spread of nosocomial pathogens: a critical look at use patterns and expectations. In: Rutala WA (editor) DSA. Washington DC: APIC, 2007, pgs. 82-96.]

APIC committee members agreed and reinforced the point that manufacturers can produce a great deal of data on inactivation of microbes on certain surfaces. By contrast, studies of efficacy in a clinical setting are very rare -- even those simply examining the ability of an antimicrobial on a surface to impact concentration and types of potential pathogens that personnel pick up on their hands during clinical care. Definitive proof demonstrating the prevention of actual healthcare associated infections (HAIs), given all the factors involved in cross transmission and host susceptibility, is even more rare. Therefore, skepticism remains related to most claims of efficacy. This continues to be reinforced by studies such as: Wood RC, et al. "Bacterial contamination of stethoscopes with antimicrobial diaphragm covers." Am J Infect Control 2007;35:263-6, that ironically found the level of bacterial contamination of the surface of stethoscopes with covers was significantly higher compared to those without covers.

Finally, another concern is the durability of surfaces that incorporate copper over time. The type of alloys involved may mitigate this issue but copper, when exposed to high levels of humidity does change from shiny copper to a green color over time (eg. when used on exteriors exposed to the elements). How well will copper alloy hold up in healthcare facilities with repeated exposure to surface disinfectants? [see especially enclosed study by Airey, et al] Also, with emergence of more virulent strains of Clostridium difficile, there is increased use of dilute bleach solutions in healthcare settings. As a result, there would need to be assurance that copper alloy can withstand this class of disinfectants.

Thank you for inquiring about the views of APIC members related to pending copper alloy product registrations. We have attached responses to your questions and to research studies that APIC public policy and practice guidance committee members felt were essential to the consideration of the claims you have pending. We hope this information is helpful.

Sincerely,

Sue Sebazco

Sue Sebazco, RN, BS, CIC
Chair, APIC Public Policy Committee

SS/lt
Enclosures (6)

DECISION PKG. NO. 372578 SUBM. DUE DATE 2/29/08

SUBMISSION BAR CODE # 818498 REVIEWER (MD)

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 8201-3 PM 33 ACTION CODE A50

DESCRIPTOR _____ **FQPA**___ **NFQPA**___

[ ] CHILD RESISTANT PACKAGING: [ ] REQUIRED [ ] NOT REQUIRED

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL [ ] RESTRICTED USE

DATE ON APPLICATION	EPA RECEIVE DATE	PM RECEIVE DATE
10,17,07	10,18,07	10,18,07

METHOD OF SUPPORT	FORMULATORS EXEMPTION
[ ] CITE-ALL [ ] SELECTIVE	[ ] SUBMITTED [ ] NOT SUBMITTED
[ ] NOT SUBMITTED [ ] N/A	[ ] N/A

REVIEW(S) REQUESTED	DATA PACK #	DATE SENT	DUE DATE	DATE RETURNED
CHEMISTRY				
EFFICACY				
ACUTE TOX.				
RASSB TOX.				
ENVIRON. FATE				
FISH/WILDLIFE				
OTHER: :				

STATUS _____

RESPONSE CODE 1170 RESPONSE DATE 02/29/08

SCIENCE GROUP	DIVISION	BRANCH	SECTION	CSF Y/N	LABEL Y/N
CHEMISTRY	AD	EASSB	CTT		
EFFICACY	AD	EASSB	EET		

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

NOTICE OF PESTICIDE:
x Registration
__ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
82012-3	022908

Term of Issuance: Conditional

Name of Pesticide Product: Antimicrobial Copper Alloys – Group III

Name and Address of Registrant (include ZIP Code):

Copper Development Association
260 Madison Avenue
New York, New York 10016-2401

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(B) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

a. Add the phrase "EPA Registration Number 82012-3."

Signature of Approving Official:

M Swindell

Marshall Swindell
Product Manager-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date: 022908

EPA Form 8570-6

The Confidential Statement of Formula dated October 4th, 2007, is acceptable.

The following are a listing of Conditions of Registration for Antimicrobial Copper Alloy registrations and associated labeling issues:

Condition 1

CDA will prepare and implement an Antimicrobial Copper Alloy Stewardship Plan ("the Plan") designed to support the responsible use of antimicrobial copper products. The Plan will be submitted for EPA review and approval within two months after the registration date. If EPA determines at any time after 18 months following registration that the Plan is not being adequately or timely implemented or that implementation of the Plan is not effectively ensuring the proper sale, distribution, or use of antimicrobial copper alloy products, the registration may be automatically cancelled by the Agency by order with no opportunity for a hearing but only after notification to the Registrant and an opportunity to meet with the Director of the Office of Pesticide Programs.

The Plan will include, at a minimum, the following elements:

(a) Outreach to the infection control community, including:

(i) A goal of educating and reinforcing, for infection control professionals and other product users, the proper use of Antimicrobial Copper Alloys.

(ii) Written (including electronic) communications directed to associations of infection control professionals, including at the least APIC, ASHES, and any other relevant organizations identified by CDA or EPA, and State Departments of Health.

(iii) Outreach communications will be sent within six months after the date of registration and within one year after the date of registration, and then annually thereafter on the anniversary of the date of the registration unless more frequent outreach is deemed necessary.

(iv) The content of the outreach communications will include statements explaining the registered claims and applications of Antimicrobial Copper Alloys, as well as their proper use. The communications also will inform the recipients about (1) the Antimicrobial Copper Alloy Working Group (see below) and invite their participation; (2) other sources of information on Antimicrobial Copper Alloys, including the Stewardship Website (see below). Additional content of outreach efforts will be developed as part of the Working Group activities.

(b) Development of a Stewardship Website ("the Website") under the auspices of the Copper Development Association ("CDA").

(i) The Website will serve as a resource for conveying accurate information to the public about the efficacy and proper use of Antimicrobial Copper Alloys.

(ii) The Website will include information on proper labeling and claims (including advertising); supporting science; applications; maintenance; and federal and state regulations and statutory requirements.

(iii) A question and answer or Frequently Asked Questions (FAQs) section will be incorporated to address common issues or questions raised with regard to Antimicrobial Copper Alloys.

(iv) The Website also will serve as a forum to correct any false or misleading third party statements or publications, including scientific papers, concerning Antimicrobial Copper Alloys. Any such false or misleading third party statements or publications will be corrected promptly after CDA or any member of CDA becomes aware of such and the responsive Website update will be incorporated promptly thereafter. CDA shall inform EPA within 30 calendar days following its receipt of any such false or misleading third party statements or publications and at that same time provide the Agency with a copy of such statement or publication along with a hard copy of the Website entry correcting such statement or publication.

(v) CDA will arrange for and establish links between the Stewardship Website and the websites of appropriate infection control organizations, including but not limited to APIC and ASHES.

(c) Establishment of an Antimicrobial Copper Alloy Working Group ("the Working Group").

(i) Invited participants will include alloy manufacturers, component makers, and representatives from the infection control community, including appropriate trade associations (*e.g.*, APIC and ASHES) and State Departments of Health.

(ii) The Working Group will meet at least twice a year, either in person or by live video conferencing (WEBEX) or teleconferencing.

(iii) The Working Group will serve as a forum to expand educational efforts, develop outreach communications, and address any questions or concerns from the public and infection control community.

(iv) CDA shall provide EPA with minutes of any such meetings within 60 days of the end of any such meeting

Condition 2

For at least the first 24 months after registration or until the Agency terminates this condition, whichever is later, the CDA will submit to EPA sample advertising materials. Advertising materials will be representative of advertisements intended for use in the marketplace.

3. Submit three (3) copies of the final printed label prior to releasing this product for sale.

A stamped copy of the label is enclosed for your records.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e) or, as may be deemed appropriate by the Agency, as provided for in Condition 1. Your release for shipment of the product constitutes acceptance of these conditions.

Sincerely,

Marshall Swindell
Product Manager 33
Regulatory Branch I
Antimicrobials Division (7510P)

Enclosure: (Stamped Labeling)

ANTIMICROBIAL COPPER ALLOYS GROUP III[+]

[+]NOTE: Product labels will bear the name of a copper alloy specified in the approved registration. Distributors may substitute a Product Brand Name in place of the name of the copper alloy on the label.

Laboratory testing has shown that when cleaned regularly:

[Antimicrobial Copper Alloys continuously reduce bacterial* contamination, achieving 99.9% reduction within two hours of exposure.]

[Antimicrobial Copper Alloys surfaces kill greater than 99.9% of Gram-negative and Gram-positive bacteria* within two hours of exposure.]

[Antimicrobial Copper Alloys surfaces deliver continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within two hours, even after repeated wet and dry abrasion and re-contamination.]

[When cleaned regularly, Antimicrobial Copper Alloys surfaces kill greater than 99.9% of bacteria* within two hours, and continue to kill more than 99% of bacteria* even after repeated contamination.]

[Antimicrobial Copper Alloys surfaces help inhibit the buildup and growth of bacteria* within two hours of exposure between routine cleaning and sanitizing steps.]

* Testing demonstrates effective antibacterial activity against *Staphylococcus aureus*, *Enterobacter aerogenes*, Methicillin-Resistant *Staphylococcus aureus* (MRSA), *Escherichia coli* O157:H7, and *Pseudomonas aeruginosa*.

The use of a Copper Alloy surface is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces. The Copper Alloy surface material has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination.

* * * * *

Active Ingredient:		
	Copper	82.6%[#]
Other		17.4%[#]

[#] Nominal percentages for purpose of review and approval. Actual percentage of copper and other ingredients will be indicated on labels distributed with the product.

Total 100%

ACCEPTED
with COMMENTS
In EPA Letter Dated:
022908
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.
82012-3

EPA Registration No. ****
EPA Establishment No. *****

Net Contents: ******

Made in the United States by *******
Distributed by *******

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[The directions in bracketed text below may be included in an insert. If so, there will be a statement to see the insert for additional directions for use of the product.]

[Directions for Use in the insert also may include installation and operation instructions, user manuals, and similar instructional materials appropriate for the end use product. No additional pesticidal claims will be made as part of these materials.]

Proper Care and Use of Antimicrobial Copper Alloys: **The use of Antimicrobial Copper Alloys does not replace standard infection control procedures and good hygienic practices. Antimicrobial Copper Alloys surfaces must be cleaned and sanitized according to standard practice.** Health care facilities must maintain the product in accordance with infection control guidelines; users must continue to follow all current infection control practices, including those practices related to disinfection of environmental surfaces.

Copper Alloy surfaces may be subject to recontamination and the level of active bacteria at any particular time will depend on the frequency and timing of recontamination and cleanliness of the surface (among other factors). In order for the copper alloy surface to have proper antimicrobial effect, the product must be cleaned and maintained according to the directions included on this label.

This product must not be waxed, painted, lacquered, varnished, or otherwise coated.

Routine cleaning to remove dirt and filth is necessary for good sanitation and to assure the effective antibacterial performance of the Antimicrobial Copper Alloy surface. Cleaning agents typically used for traditional touching surfaces are permissible; the appropriate cleaning agent depends on the type of soiling and the measure of sanitization required. [Normal tarnishing or wear of Antimicrobial Copper Alloy surfaces will not impair the antibacterial effectiveness of the product.]

This product can not be used for any direct food contact or food packaging uses.

[Antimicrobial Copper Alloys may be used in hospitals, other healthcare facilities, and various public, commercial, and residential buildings for the non-food contact surfaces listed below.] [The following statement will appear on the label if the use involves potential exposure to outdoor conditions: Surfaces that may be exposed to outdoor environmental conditions (*e.g.*, handrails, shopping carts, child seats and ATM machines) are not representative of indoor laboratory test conditions, and therefore, may impart reduced efficacy if not cleaned when visibly soiled.]

Healthcare Facilities

- Bedrails, footboards
- Over-bed tables
- Bed-side tables in hospitals, extended care facilities, senior housing etc. (knobs, pulls, handles; surfaces)

ACCEPTED
with COMMENTS
In EPA Letter Dated:
022908
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.
82012-3

- Handrails, (corridor/hallways) (Senior housing), automatic door push plates
- Stair rails, handrails, tubular railing, and supports, rail fittings T's, elbows and brackets
- Bedrails, assistance rails,
- Toilet safety rails
- Carts
  - Hospital carts (table surfaces, handles, legs)
  - Computer carts
  - Record carts
  - Phlebotomy carts
  - Other Carts (tables/surfaces, shelving, railings, handles, pulls)
- Equipment carts (horizontal surfaces, frames, handles)
- Door push plates, kick plates, mop plates, stretcher plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Water fountains: bubbler head, drain strainer, handle
- Alcohol sanitizer dispenser, handle
- Paper towel holders, facial tissue holders, toilet paper holders
- Air hand dryer, controls and push buttons on air hand dryers
- Hydrotherapy tanks (whirlpool tanks): shells, covers, headrests, drain fittings (outer surfaces without water contact)
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Panic bars on emergency room doors
- Towel bars
- Showerheads
- Countertops and tabletops (non-food use only)
- Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Closures
- Vertical locking arms
- Vertical cover guards
- Protection bars
- Light switches, switch plates
- Visitor chairs: armrests, metal frames
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Floor tiles
- Ceiling tiles (non-porous)
- Wall tiles
- Instrument handles

Medical equipment knobs, pulls and handles for:

ACCEPTED
with COMMENTS
In EPA Letter Dated:
022908
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.
82012-3

- Drug delivery systems
- Monitoring systems
- Hospital beds
- Office equipment
- Operating room equipment
- Stands and fixtures

Types of knobs: *e.g.*, Prong, fluted, knurled, push/pull, T-handle, tapered, and ball knobs

- Intravenous (IV) poles, bases, hangers, clips
- Trays (instruments, non-food contact)
- Pans (bed)
- Walkers, wheelchair handles, and tubular components
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise and rehabilitation equipment, handles, bars
- Physical therapy equipment: physical therapy tables, treatment chairs and portable taping tables
- Chairs (shower chairs, patient chairs, visitor chairs): rails, backs, legs, seats
- Lighting products: X-ray illuminators, operating rooms, patient examination rooms, surgical suites, and reading lamps for hospital rooms and assisted living facilities etc. Components can include bases, arms, housings, handles, hinges)
- Headwall systems: the unit themselves, outlet covers, knobs and dials, lighting units (lamp housings and adjustable arms), CRT monitors with rotating knobs and levers and adjustments. Baskets, monitor housings, knobs, baskets, tables, IV poles
- Critical care cart: Table top, drawer, drawer pull, lock, copper wire baskets for storage of equipment and charts.
- Bedside lavatory: sink, faucet, handles, drawer pulls, toilet seat, toilet seat cover, toilet handle, door and cabinet facings, counter tops
- Medical records: Chart holders, clipboards, filing systems
- Storage Shelving: wire shelving etc. for medical supplies
- Grab handles on privacy curtains
- Lids of laundry hampers, trash canisters, and other containers

Community Facilities (including various public and commercial buildings)

- Shopping cart handles, child seats, handrails
- Cash registers: housing, keypads
- ATM machines: keys, housing
- Gym/Health club lockers, locker handles, locker shelving, trainers' tables,
- Ice and water dispensers (outer surfaces without water contact)
- Elevator: handrail, control panel, buttons, interior walls, floor tiles, exterior call button plate
- Paper towel dispensers. Housing itself, (turn) handle, (push) handle
- Soap holder
- Soap dispenser (wall mounted): push bar and dispenser itself
- Soap dispenser (sitting on counter): dispenser housing itself, push mechanism
- Toilet paper dispenser (housing)
- Windows (crank), Locking mechanism, pull handles

- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)
- Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)
- Light switches, switch plates
- Lids of laundry hampers, trash canisters, and other containers

Residential Buildings (including homes, apartments, apartment buildings and other residences)

- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Bedrails, footboards
- Handrails
- Stair rails
- Door push plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Paper towel holders, facial tissue holders, toilet paper holders
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Towel bars
- Showerheads
- Countertops and tabletops
- Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Light switches, switch plates
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- Floor tiles
- Ceiling tiles (non-porous)
- Wall tiles
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise equipment, handles, bars
- Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)
- Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)
- Television control knobs and buttons
- Lids of laundry hampers, trash canisters, and other containers

ACCEPTED
with COMMENTS
In EPA Letter Dated:

02 29 08

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

82012-5

Other

- Play area equipment (indoor only): bars, handles, chains, push plates, handrails, stair rails and risers, wheels, knobs, flooring

STORAGE AND DISPOSAL

Antimicrobial Copper Alloys should be disposed in a responsible manner, including recycling.

WARRANTY STATEMENT

If used as intended, Antimicrobial Copper Alloys are wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.

ACCEPTED
with COMMENTS
In EPA Letter Dated:
022908

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.
82012-3

Philip Ross/DC/USEPA/US
02/27/2008 02:44 PM

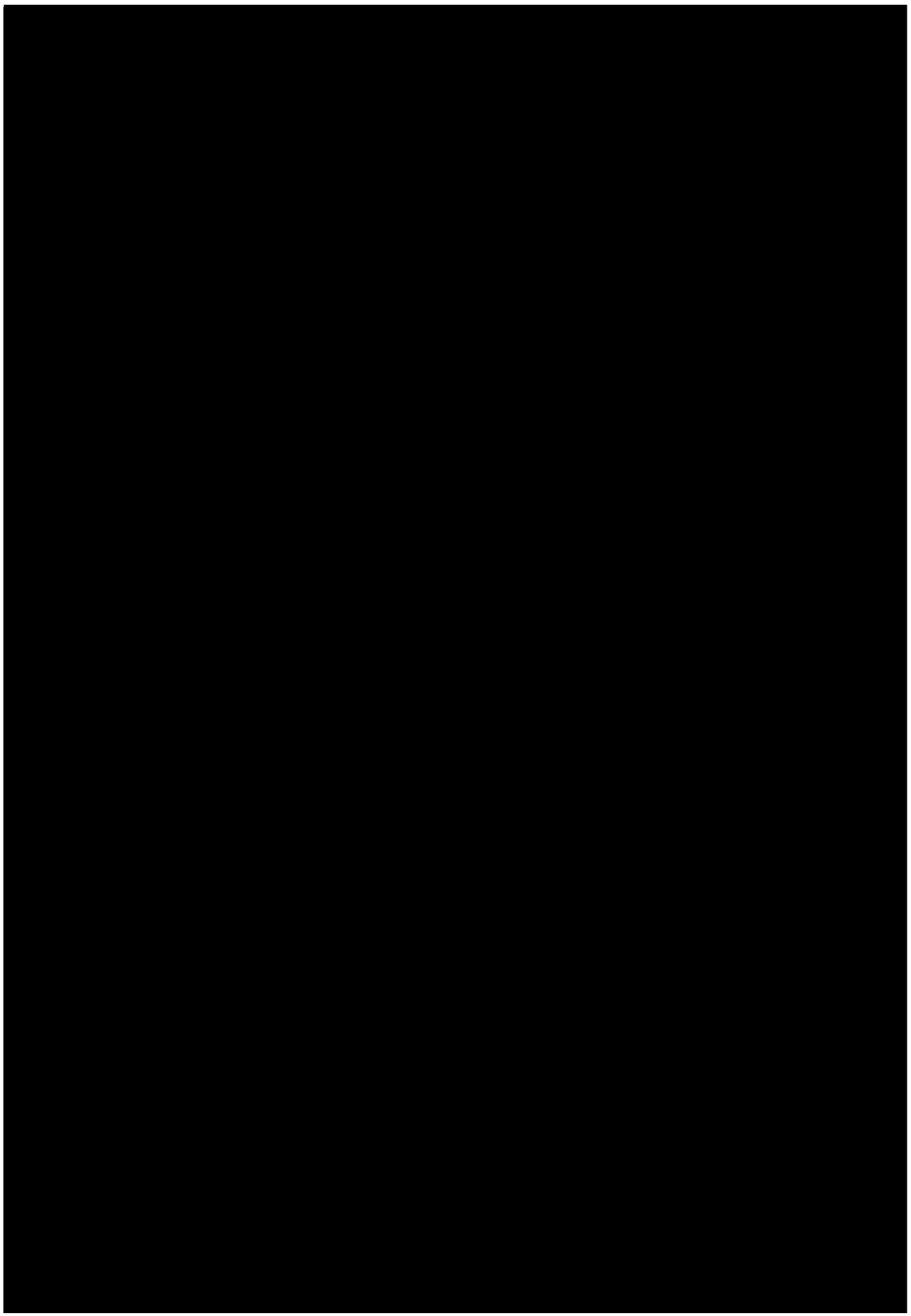
To William Jordan/DC/USEPA/US@EPA, Robert Perlis/DC/USEPA/US@EPA, Dennis Edwards/DC/USEPA/US@EPA, Betty
cc Karen Leavy/DC/USEPA/US@EPA, Marcie Tidd/DC/USEPA/US@EPA, Robert Perlis/DC/USEPA/US@EPA
bcc

Subject Re: Fw: Antimicrobial Copper Alloys - Registration Conditions and Revised Labels

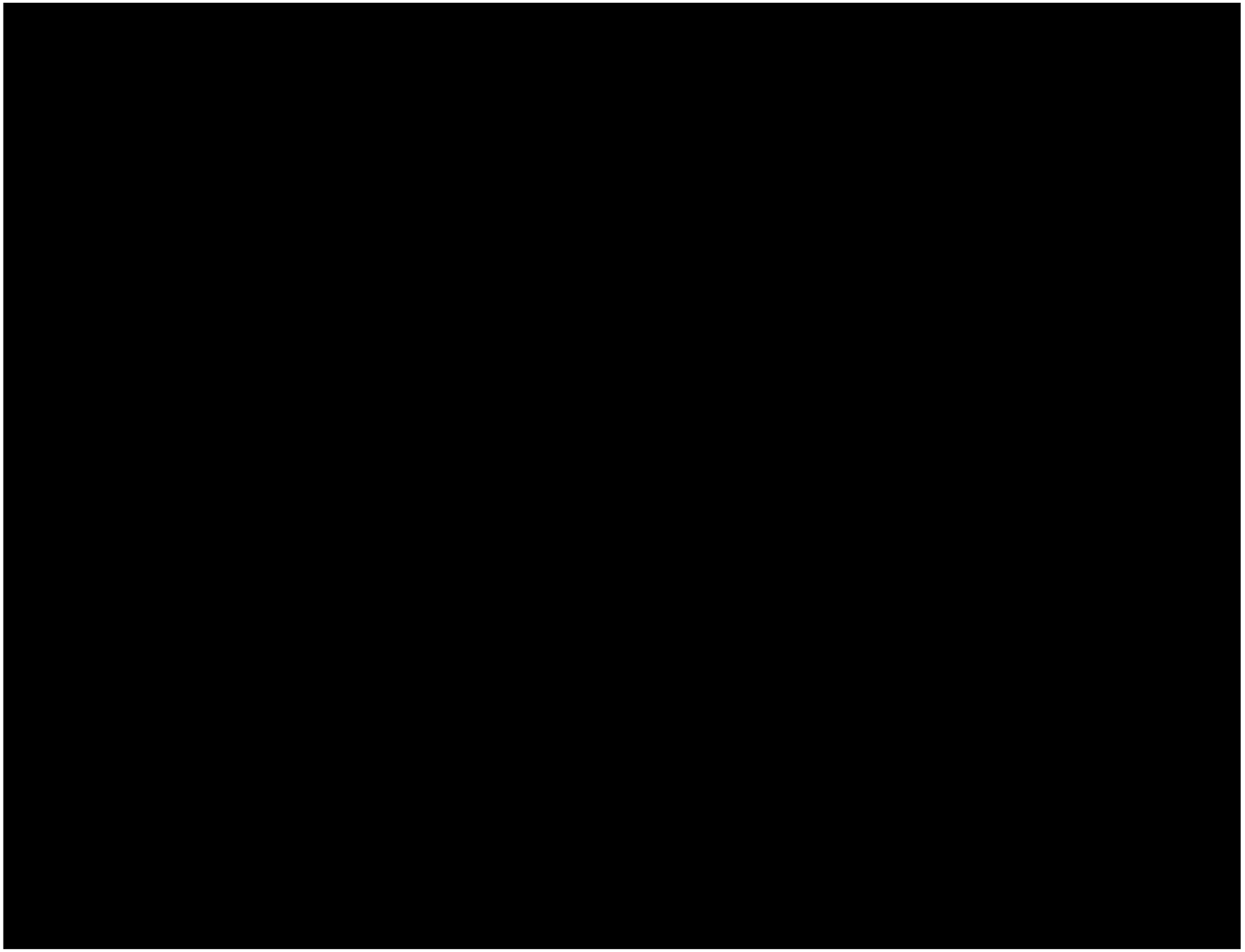
Attorney Client Communication
Attorney Work Product
Deliberative
Privileged and Confidential
Do Not Release

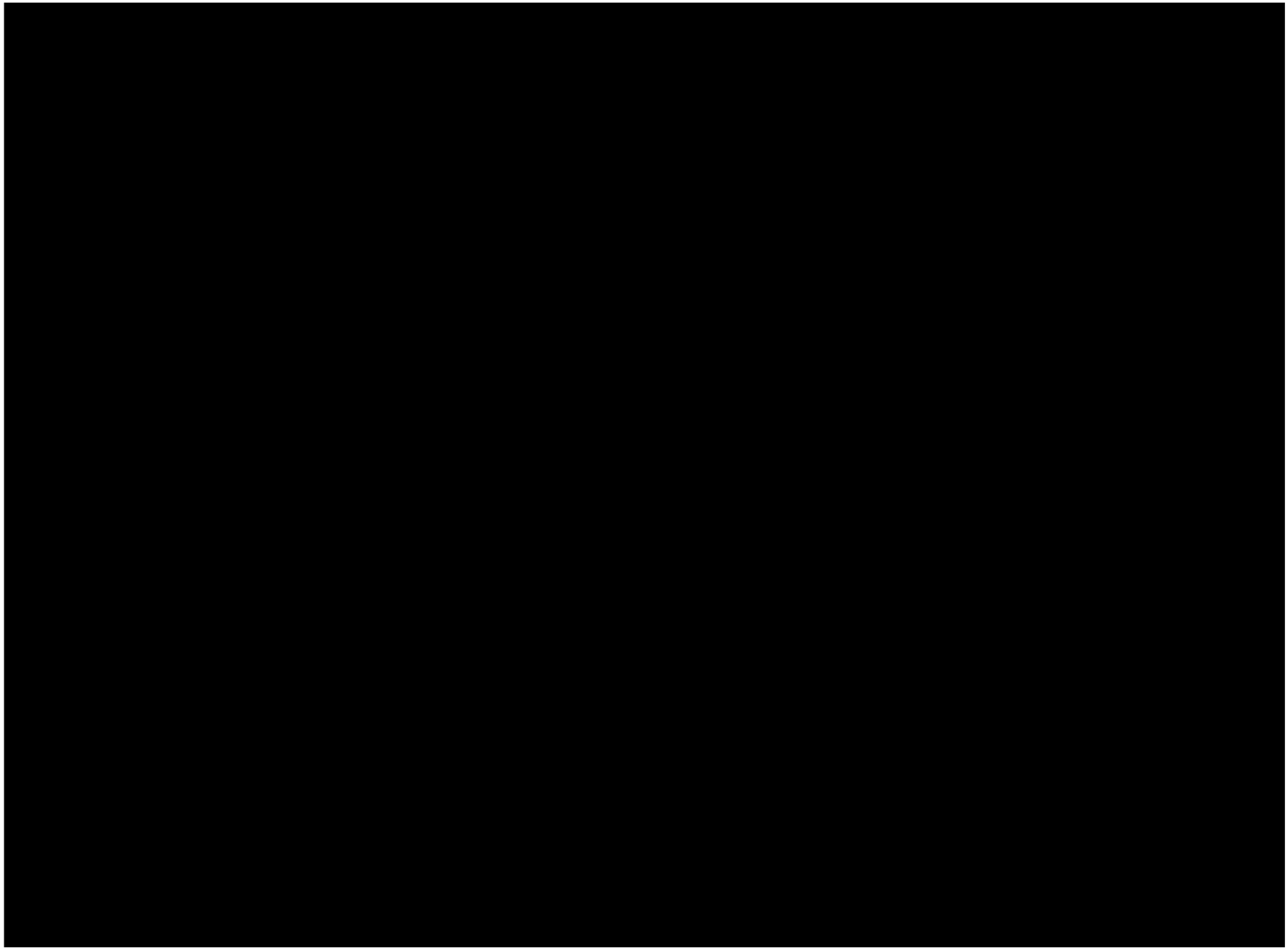
[redacted]

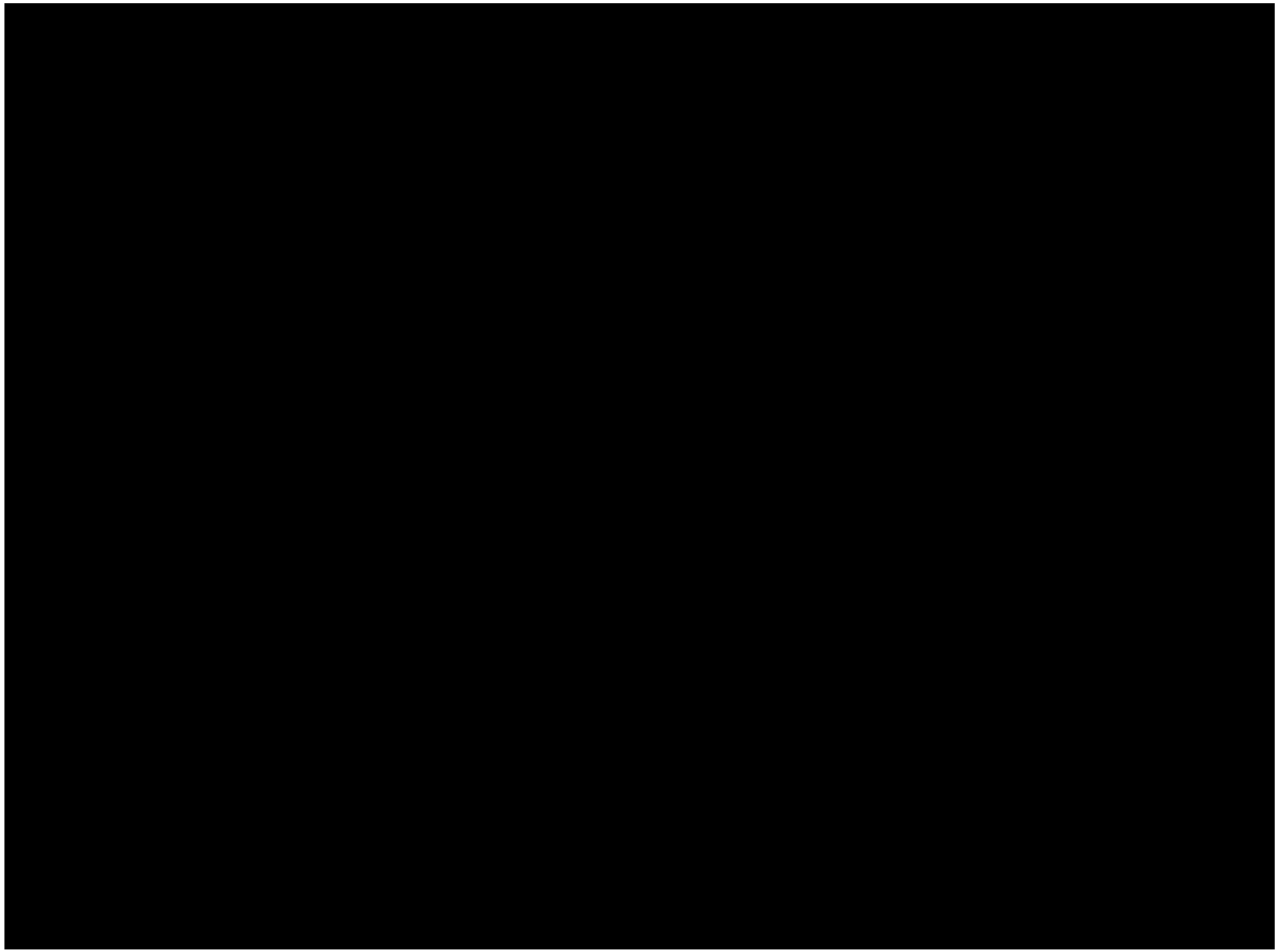
Privileged internal deliberative and attorney-client communication



Privileged internal deliberative and attorney-client communication







Privileged internal deliberative and attorney-client communication

[redacted]

Philip J. Ross
United States Environmental Protection Agency
Office of General Counsel
Pesticides and Toxic Substances Law Office
202-564-5637

William Jordan/DC/USEPA/US

William
Jordan/DC/USEPA/US
02/27/2008 02:04 PM

To Karen Leavy/DC/USEPA/US@EPA
cc Marcie Tidd/DC/USEPA/US@EPA, Philip Ross/DC/USEPA/US@EPA, Robert Perlis/DC/USEPA/US@EPA
Subject Re: Fw: Antimicrobial Copper Alloys - Registration Conditions and Revised Labels

[redacted]

Privileged internal deliberative communication

[redacted]

Bill

William L. Jordan
Senior Policy Adviser
Office of Pesticide Programs -- Mail code 7501P
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
(703) 305-1049 (voice)
(703) 308-4776 (fax)
Karen Leavy/DC/USEPA/US

Karen Leavy/DC/USEPA/US

02/27/2008 01:36 PM

To Philip Ross/DC/USEPA/US@EPA, Robert Perlis/DC/USEPA/US@EPA, William Jordan/DC/USEPA/US@EPA, Marcie Tidd/DC/USEPA/US@EPA

cc

Subject Fw: Antimicrobial Copper Alloys - Registration Conditions and Revised Labels

Hello everyone,

Here is CDA's proposal(s) for conditions to registration which include revised labeling.
Please read attachments below.

KML

----Forwarded by Karen Leavy/DC/USEPA/US on 02/27/2008 01:30PM ----

To: Dennis Edwards/DC/USEPA/US@EPA

From: "Green, Joseph J." <JGreen@KelleyDrye.com>
Date: 02/26/2008 07:13PM
cc: Marshall Swindell/DC/USEPA/US@EPA, Karen Leavy/DC/USEPA/US@EPA, "Michels, Harold" <hmichels@cda.copper.org>, "Robert Stewart" <RStewart@TSGUSA.COM>, "Doug Anderson" <doug.anderson@ATS-Labs.com>
Subject: Antimicrobial Copper Alloys - Registration Conditions and Revised Labels

Dennis -

Attached are several documents as we discussed at our meeting today. They include:

(1) A letter proposing registration conditions and discussing the revised label. (Plus an attached chart)

(2) A revised proposed Master Label; and

(3) A revised proposed End User label.

I believe the revised labels convey accurately and with minimal risk of confusion the label claims and "disclaimer" language we have discussed. In particular, I think the End User label may be particularly helpful in demonstrating that the "disclaimer" language will be prominent.

We are, of course, anxious for your feedback and remain hopeful that we can come to a mutually satisfactory final determination by this Friday's PRIA deadline.

Thanks again for your attention to this matter.

Regards,
Joe

Joseph J. Green
Kelley Drye Collier Shannon
3050 K Street, N.W.
Washington, D.C. 20007
202.342.8849
Fax: 202.342.8451
www.kelleydrye.com

other defect that might affect any computer system into which it is received and opened. However, it is the responsibility of the recipient to ensure that it is virus free and no responsibility is accepted by Kelley Drye & Warren LLP for any loss or damage arising in any way from its use.

DC01-328629-v1-Antimicrobial Copper Alloys Registration Conditions and Revised Label.DOC

Tarnish C110 220 770.ppt

DC01-328649-v1-Proposed master Label - Antimicrobial Copper Alloys (February 2008).DOC

DC01-328657-v1-Proposed End User Label - Antimicrobial Copper Alloys (February 2008).DOC

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

2/29/2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Hi Joe,

Our OGC made 2 changes to the conditions when they reviewed the registration notice for these products. Since changes were made I need your concurrence that the changes are ok.

1) Slight rewording of c(5) to read "CDA shall provide EPA with minutes of any such meetings within 60 days of the end of such meeting."

2). Standard language in a registration notice is the statement "If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e)." OGC has added the following phrase to the end of the above sentence "or as may be deemed appropriate by the Agency, as provided for in condition 1". So the sentence will now read:

"If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e) or as may be deemed appropriate by the Agency, as provided for in condition 1."

Please fax this document and attached pages back to me (703-308-6467). You need initial each page and include a statement that these changes are acceptable to CDA.

Thanks
Dennis

Dennis- Those changes are acceptable to CDA.
Counsel to CDA

The Confidential Statement of Formula dated October 4th, 2007, is acceptable.

The following are a listing of Conditions of Registration for Antimicrobial Copper Alloy registrations and associated labeling issues:

Condition 1

CDA will prepare and implement an Antimicrobial Copper Alloy Stewardship Plan ("the Plan") designed to support the responsible use of antimicrobial copper products. The Plan will be submitted for EPA review and approval within two months after the registration date. If EPA determines at any time after 18 months following registration that the Plan is not being adequately or timely implemented or that implementation of the Plan is not effectively ensuring the proper sale, distribution, or use of antimicrobial copper alloy products, the registration may be automatically cancelled by the Agency by order with no opportunity for a hearing but only after notification to the Registrant and an opportunity to meet with the Director of the Office of Pesticide Programs.

The Plan will include, at a minimum, the following elements:

(a) Outreach to the infection control community, including:

(i) A goal of educating and reinforcing, for infection control professionals and other product users, the proper use of Antimicrobial Copper Alloys.

(ii) Written (including electronic) communications directed to associations of infection control professionals, including at the least APIC, ASHES, and any other relevant organizations identified by CDA or EPA, and State Departments of Health.

(iii) Outreach communications will be sent within six months after the date of registration and within one year after the date of registration, and then annually thereafter on the anniversary of the date of the registration unless more frequent outreach is deemed necessary.

(iv) The content of the outreach communications will include statements explaining the registered claims and applications of Antimicrobial Copper Alloys, as well as their proper use. The communications also will inform the recipients about (1) the Antimicrobial Copper Alloy Working Group (see below) and invite their participation; (2) other sources of information on Antimicrobial Copper Alloys, including the Stewardship Website (see below). Additional content of outreach efforts will be developed as part of the Working Group activities.

Acceptable to CDA

(ii) The Website will include information on proper labeling and claims (including advertising); supporting science; applications; maintenance; and federal and state regulations and statutory requirements.

(iii) A question and answer or Frequently Asked Questions (FAQs) section will be incorporated to address common issues or questions raised with regard to Antimicrobial Copper Alloys.

(iv) The Website also will serve as a forum to correct any false or misleading third party statements or publications, including scientific papers, concerning Antimicrobial Copper Alloys. Any such false or misleading third party statements or publications will be corrected promptly after CDA or any member of CDA becomes aware of such and the responsive Website update will be incorporated promptly thereafter. CDA shall inform EPA within 30 calendar days following its receipt of any such false or misleading third party statements or publications and at that same time provide the Agency with a copy of such statement or publication along with a hard copy of the Website entry correcting such statement or publication.

(v) CDA will arrange for and establish links between the Stewardship Website and the websites of appropriate infection control organizations, including but not limited to APIC and ASHES.

(c) Establishment of an Antimicrobial Copper Alloy Working Group ("the Working Group").

(i) Invited participants will include alloy manufacturers, component makers, and representatives from the infection control community, including appropriate trade associations (*e.g.*, APIC and ASHES) and State Departments of Health.

(ii) The Working Group will meet at least twice a year, either in person or by live video conferencing (WEBEX) or teleconferencing.

(iii) The Working Group will serve as a forum to expand educational efforts, develop outreach communications, and address any questions or concerns from the public and infection control community.

(iv) CDA shall provide EPA with minutes of any such meetings within 60 days of the end of any such meeting

Condition 2

For at least the first 24 months after registration or until the Agency terminates this condition, whichever is later, the CDA will submit to EPA sample advertising materials. Advertising materials will be representative of advertisements intended for use in the marketplace.

Accepted SCDA.

Condition 2

For at least the first 24 months after registration or until the Agency terminates this condition, whichever is later, the CDA will submit to EPA sample advertising materials. Advertising materials will be representative of advertisements intended for use in the marketplace.

3. Submit three (3) copies of the final printed label prior to releasing this product for sale.

A stamped copy of the label is enclosed for your records.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e) or as may be deemed appropriate by the Agency, as provided for in Condition 1. Your release for shipment of the product constitutes acceptance of these conditions.

Sincerely,

Marshall Swindell
Product Manager 33
Regulatory Branch I
Antimicrobials Division (7510P)

Enclosure: (Stamped Labeling)

Acceptable to CDA.

[redacted]

Marcie Tidd/DC/USEPA/US
02/27/2008 06:30 PM

To Dennis Edwards/DC/USEPA/US@EPA
cc Michele Wingfield/DC/USEPA/US@EPA, Karen Leavy/DC/USEPA/US@EPA, Betty Shackleford/DC/USEPA/US@EPA
bcc
Subject Re: Fw: Antimicrobial Copper Alloys - Registration Conditions and Revised Labels

[redacted]

Privileged internal deliberative communication

[redacted]

Thanks,

Marcie Tidd
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Phone: 703-308-0173
Fax: 703-308-8481
Email: tidd.marcie@epa.gov
Philip Ross/DC/USEPA/US

Philip Ross/DC/USEPA/US
02/27/2008 03:16 PM

To Philip Ross/DC/USEPA/US@EPA

cc Betty Shackleford/DC/USEPA/US@EPA, Dennis Edwards/DC/USEPA/US@EPA, Karen Leavy/DC/USEPA/US@EPA, Marcie Tidd/DC/USEPA/US@EPA, Robert Perlis/DC/USEPA/US@EPA, William Jordan/DC/USEPA/US@EPA

Subject Re: Fw: Antimicrobial Copper Alloys - Registration Conditions and Revised Labels

Attorney Client Communication
Attorney Work Product
Deliberative
Privileged and Confidential
Do Not Release

[redacted]

Privileged internal deliberative and attorney-client communication

[redacted]

Philip J. Ross
United States Environmental Protection Agency
Office of General Counsel
Pesticides and Toxic Substances Law Office
202-564-5637

Philip Ross/DC/USEPA/US

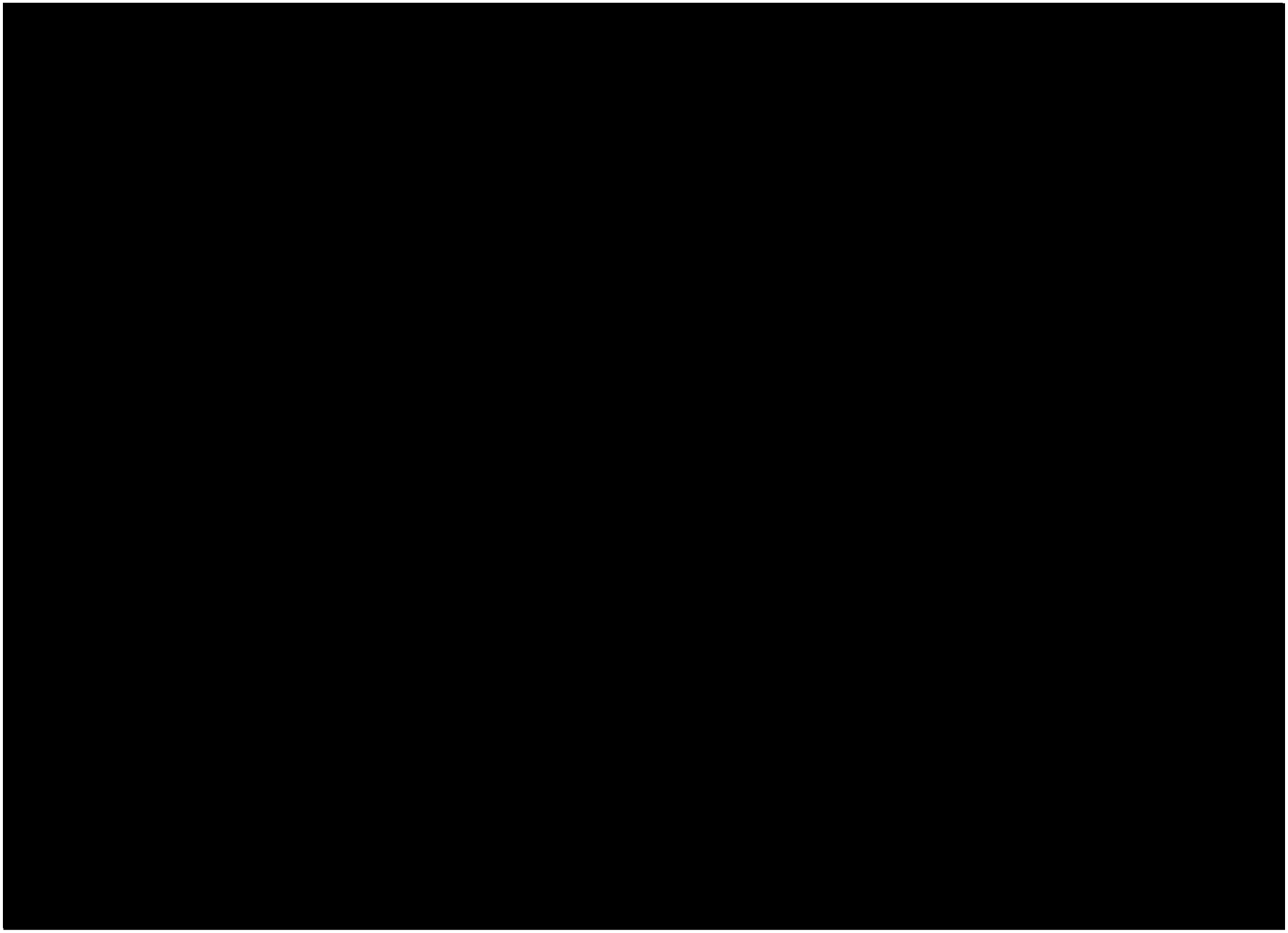
Philip Ross/DC/USEPA/US
02/27/2008 02:44 PM

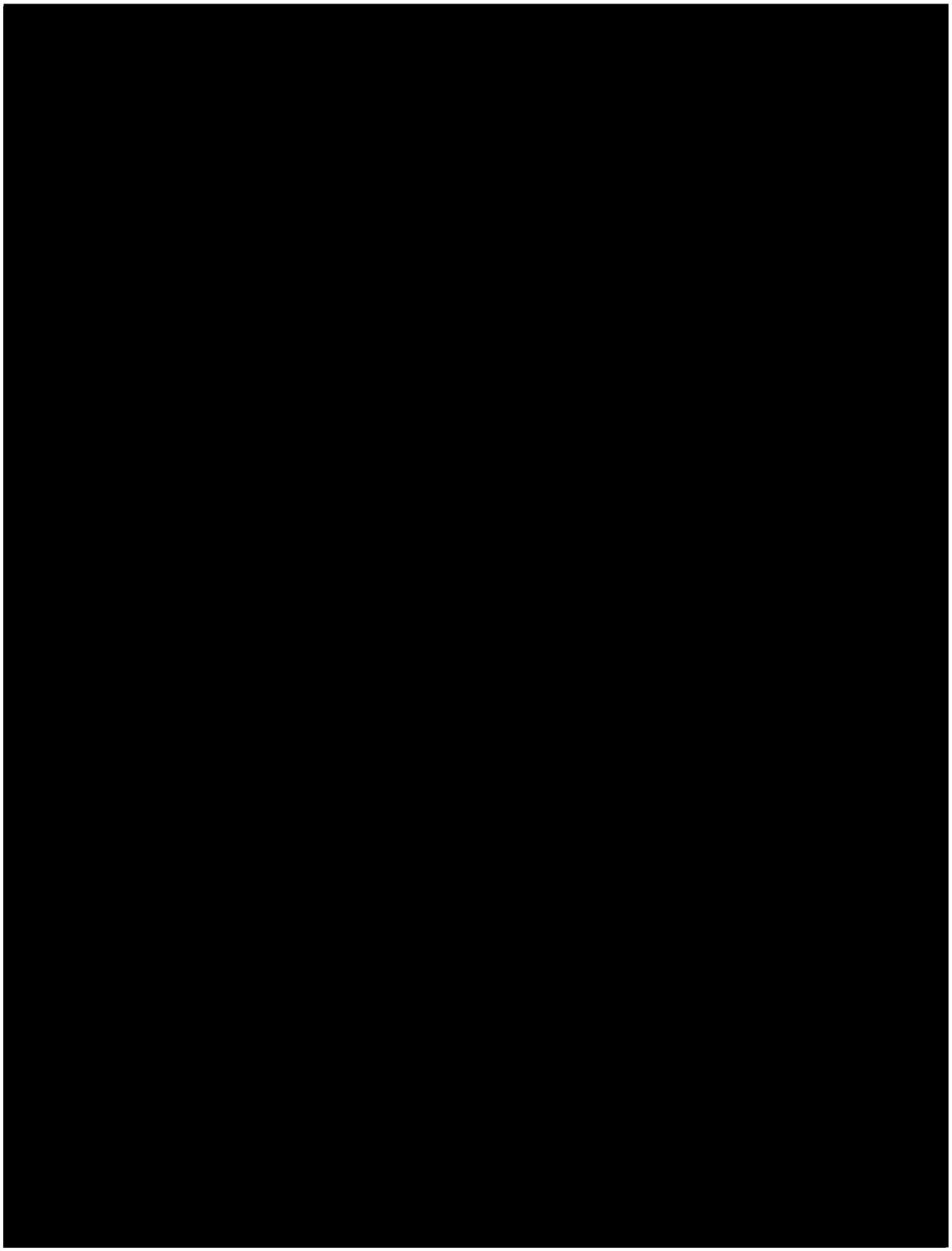
To William Jordan/DC/USEPA/US, Robert Perlis/DC/USEPA/US, Dennis Edwards/DC/USEPA/US, Betty Shackleford/DC/USEPA/US
cc Karen Leavy/DC/USEPA/US@EPA, Marcie Tidd/DC/USEPA/US@EPA, Robert Perlis/DC/USEPA/US@EPA
Subject Re: Fw: Antimicrobial Copper Alloys - Registration Conditions and Revised Labels

Attorney Client Communication
Attorney Work Product
Deliberative
Privileged and Confidential
Do Not Release

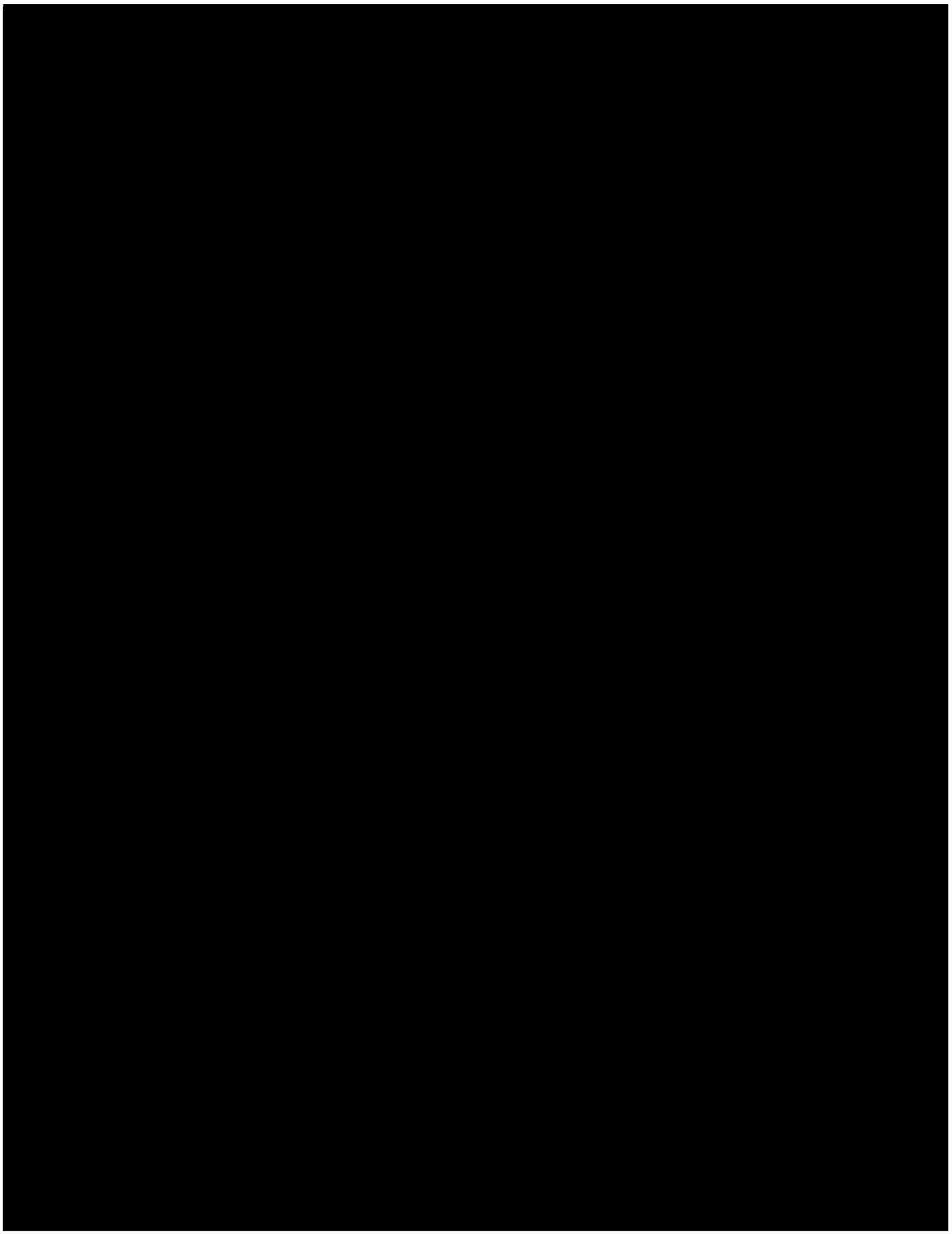
[redacted]

Privileged internal deliberative and attorney-client communication

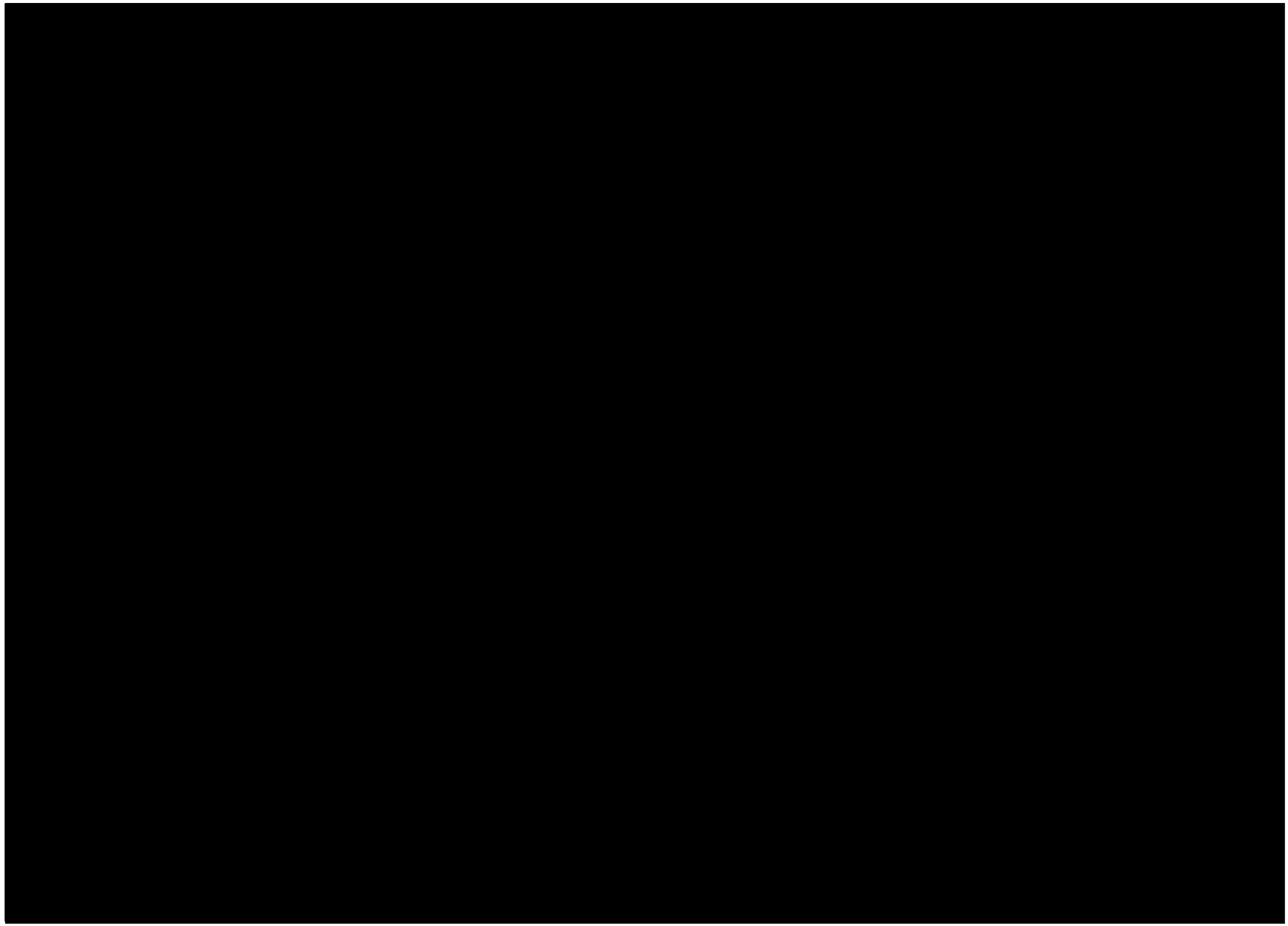




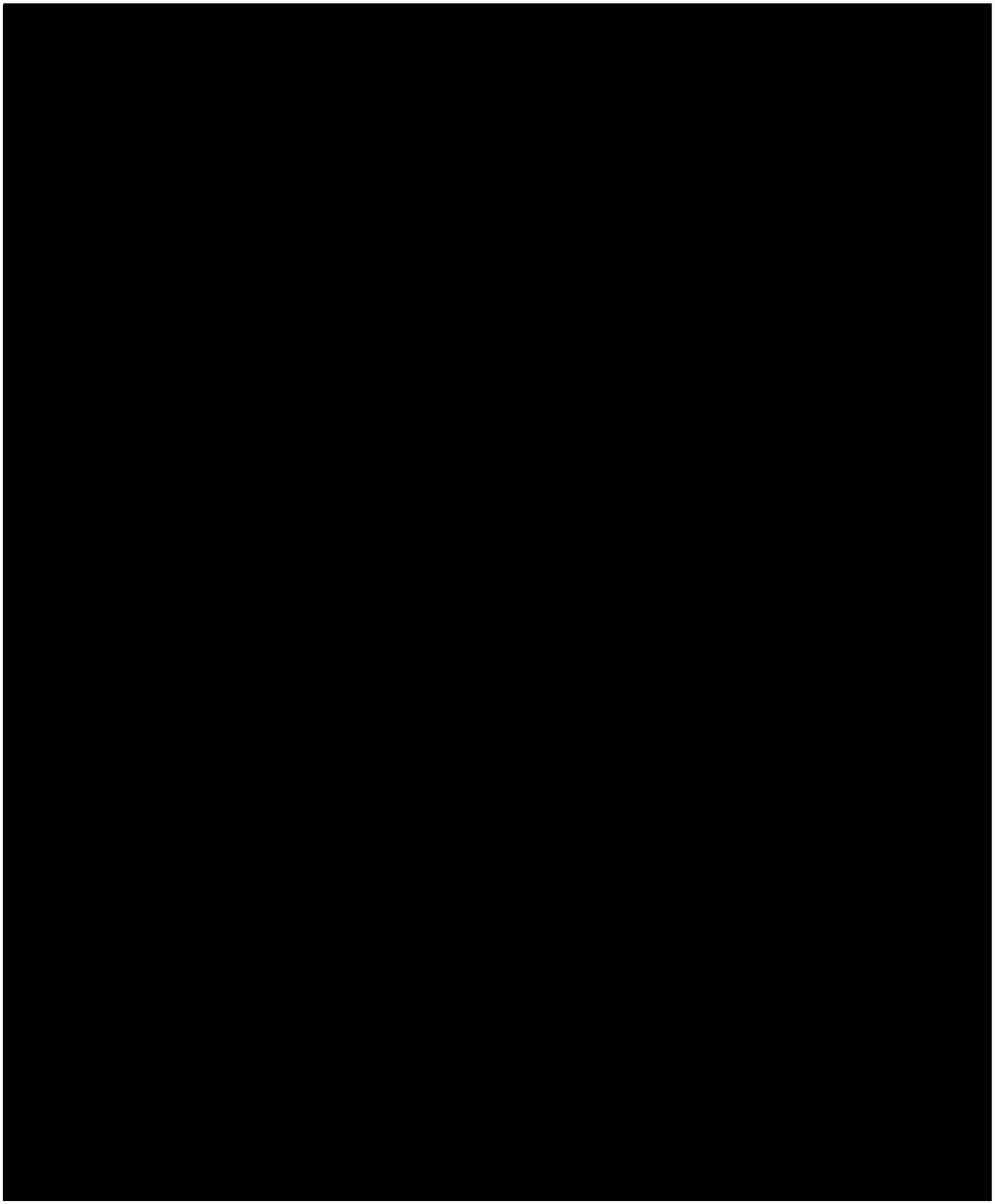
Privileged internal deliberative and attorney-client communication



Privileged internal deliberative and attorney-client communication



Privileged internal deliberative and attorney-client communication



Philip J. Ross
United States Environmental Protection Agency

Office of General Counsel
Pesticides and Toxic Substances Law Office
202-564-5637

William Jordan/DC/USEPA/US

William
Jordan/DC/USEPA/US
02/27/2008 02:04 PM

To Karen Leavy/DC/USEPA/US@EPA

cc Marcie Tidd/DC/USEPA/US@EPA, Philip Ross/DC/USEPA/US@EPA, Robert Perlis/DC/USEPA/US@EPA

Subject Re: Fw: Antimicrobial Copper Alloys - Registration Conditions and Revised Labels

Privileged internal deliberative communication

[redacted]

Bill

William L. Jordan
Senior Policy Adviser
Office of Pesticide Programs -- Mail code 7501P
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
(703) 305-1049 (voice)
(703) 308-4776 (fax)

Office of General Counsel
Pesticides and Toxic Substances Law Office
202-564-5637

William Jordan/DC/USEPA/US

William
Jordan/DC/USEPA/US
02/27/2008 02:04 PM

To Karen Leavy/DC/USEPA/US@EPA

cc Marcie Tidd/DC/USEPA/US@EPA, Philip Ross/DC/USEPA/US@EPA, Robert Perlis/DC/USEPA/US@EPA

Subject Re: Fw: Antimicrobial Copper Alloys - Registration Conditions and Revised Labels

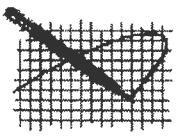
Privileged internal deliberative communication

[redacted]

Bill

William L. Jordan
Senior Policy Adviser
Office of Pesticide Programs – Mail code 7501P
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
(703) 305-1049 (voice)
(703) 308-4776 (fax)

Karen Leavy/DC/USEPA/US



Karen Leavy/DC/USEPA/US

02/27/2008 01:36 PM

To Philip Ross/DC/USEPA/US@EPA, Robert Perlis/DC/USEPA/US@EPA, William Jordan/DC/USEPA/US@EPA, Marcie Tidd/DC/USEPA/US@EPA

cc

Subject Fw: Antimicrobial Copper Alloys - Registration Conditions and Revised Labels

Hello everyone,

Here is CDA's proposal(s) for conditions to registration which include revised labeling.
Please read attachments below.

KML

----Forwarded by Karen Leavy/DC/USEPA/US on 02/27/2008 01:30PM -----

To: Dennis Edwards/DC/USEPA/US@EPA
From: "Green, Joseph J." <JGreen@KelleyDrye.com>
Date: 02/26/2008 07:13PM
cc: Marshall Swindell/DC/USEPA/US@EPA, Karen Leavy/DC/USEPA/US@EPA, "Michels, Harold" <hmichels@cda.copper.org>, "Robert Stewart" <RStewart@TSGUSA.COM>, "Doug Anderson" <doug.anderson@ATS-Labs.com>
Subject: Antimicrobial Copper Alloys - Registration Conditions and Revised Labels

Dennis -

Attached are several documents as we discussed at our meeting today. They include:

(1) A letter proposing registration conditions and discussing the revised label. (Plus an attached chart)

(2) A revised proposed Master Label; and

(3) A revised proposed End User label.

I believe the revised labels convey accurately and with minimal risk of confusion the label claims and "disclaimer" language we have discussed. In particular, I think the End User label may be particularly helpful in demonstrating that the "disclaimer" language will be prominent.

We are, of course, anxious for your feedback and remain hopeful that we can come to a mutually satisfactory final determination by this Friday's PRIA deadline.

Thanks again for your attention to this matter.

Regards,
Joe

Joseph J. Green
Kelley Drye Collier Shannon

3050 K Street, N.W.
Washington, D.C. 20007
202.342.8849
Fax: 202.342.8451
www.kelleydrye.com

Dennis
Edwards/DC/USEPA/US
02/29/2008 09:25 AM

To JGreen@KelleyDrye.com
cc Marshall Swindell/DC/USEPA/US@EPA, Karen Leavy/DC/USEPA/US@EPA, Philip Ross/DC/USEPA/US@EPA, Robert
bcc
Subject Antimicrobial Copper Alloys - Registration Conditions

Hi Joe,

Thank you for developing proposed conditions of registration for the proposed Antimicrobial Copper Alloys registrations as a follow-up to our February 26, 2008 meeting. We have reviewed your proposed registration conditions transmitted by e-mail on February 26.

Attached as a Word file are our modifications to your proposed registration conditions that we believe will enable us, today, to issue registrations for the five proposed copper alloy products. Please review these registration conditions and let me know if these are acceptable to CDA. I will be glad to discuss these registration conditions with you and a provide a rationale for our modifications.

We have also included three additional label comments. Revised labels for the 5 proposed copper alloy products should be submitted incorporating these comments as well as the label modifications you submitted on February 27.

If we you need additional time to review these proposals beyond today, please provide us with a request to extend the due date. Note that our internal procedures require that we obtain sign off for time extensions. Therefore, we will need a request by mid afternoon in order to get the necessary approval.

copper alloy contition of reg.2-29-08.doc

Dennis Edwards, Chief
Regulatory Management Branch 1
Antimicrobials Division
703-308-8087

Proposed Conditions of Registration for Antimicrobial Copper Alloy registrations and associated labeling issues.

Condition 1

CDA will prepare and implement an Antimicrobial Copper Alloy Stewardship Plan ("the Plan") designed to support the responsible use of antimicrobial copper products. The Plan will be submitted for EPA review and approval within two months after the registration date. If EPA determines at any time after 18 months following registration that the Plan is not being adequately or timely implemented or that implementation of the Plan is not effectively ensuring the proper sale, distribution, or use of antimicrobial copper alloy products, the registration may be automatically cancelled by the Agency by order with no opportunity for a hearing but only after notification to the Registrant and an opportunity to meet with the Director of the Office of Pesticide Programs.

The Plan will include, at a minimum, the following elements:

(a) Outreach to the infection control community, including:

(i) A goal of educating and reinforcing, for infection control professionals and other product users, the proper use of Antimicrobial Copper Alloys.

(ii) Written (including electronic) communications directed to associations of infection control professionals, including at the least APIC, ASHES, and any other relevant organizations identified by CDA or EPA, and State Departments of Health.

(iii) Outreach communications will be sent within six months after the date of registration and within one year after the date of registration, and then annually thereafter on the anniversary of the date of the registration unless more frequent outreach is deemed necessary.

(iv) The content of the outreach communications will include statements explaining the registered claims and applications of Antimicrobial Copper Alloys, as well as their proper use. The communications also will inform the recipients about (1) the Antimicrobial Copper Alloy Working Group (see below) and invite their participation; (2) other sources of information on Antimicrobial Copper Alloys, including the Stewardship Website (see below). Additional content of outreach efforts will be developed as part of the Working Group activities.

(b) Development of a Stewardship Website ("the Website") under the auspices of the Copper Development Association ("CDA").

(i) The Website will serve as a resource for conveying accurate information to the public about the efficacy and proper use of Antimicrobial Copper Alloys.

(ii) The Website will include information on proper labeling and claims (including advertising); supporting science; applications; maintenance; and federal and state regulations and statutory requirements.

(iii) A question and answer or Frequently Asked Questions (FAQs) section will be incorporated to address common issues or questions raised with regard to Antimicrobial Copper Alloys.

(iv) The Website also will serve as a forum to correct any false or misleading third party statements or publications, including scientific papers, concerning Antimicrobial Copper Alloys. Any such false or misleading third party statements or publications will be corrected promptly after CDA or any member of CDA becomes aware of such and the responsive Website update will be incorporated promptly thereafter. CDA shall inform EPA within 30 calendar days following its receipt of any such false or misleading third party statements or publications and at that same time provide the Agency with a copy of such statement or publication along with a hard copy of the Website entry correcting such statement or publication.

(v) CDA will arrange for and establish links between the Stewardship Website and the websites of appropriate infection control organizations, including but not limited to APIC and ASHES.

(c) Establishment of an Antimicrobial Copper Alloy Working Group ("the Working Group").

(i) Invited participants will include alloy manufacturers, component makers, and representatives from the infection control community, including appropriate trade associations (*e.g.*, APIC and ASHES) and State Departments of Health.

(ii) The Working Group will meet at least twice a year, either in person or by live video conferencing (WEBEX) or teleconferencing.

(iii) The Working Group will serve as a forum to expand educational efforts, develop outreach communications, and address any questions or concerns from the public and infection control community.

(iv) CDA shall provide EPA with minutes of any such meetings within 60 days of the end of such meetings.

Condition 2

For at least the first 24 months after registration or until the Agency terminates this condition, whichever is later, the CDA will submit to EPA sample advertising materials. Advertising materials will be representative of advertisements intended for use in the marketplace.

Remaining labeling issues:

1) On the front panel of the label revised the statement "Laboratory testing has shown that:" to read "Laboratory testing has shown that when cleaned regularly:"

or

Add the phrase "when cleaned regularly" to the beginning of each claim listed on the label. The first claim would read "When cleaned regularly, Antimicrobial Copper Alloys continuously reduce bacterial* contamination, achieving 99.9% reduction within two hours of exposure."

2) On the front panel of the label, add the statement listed below to the end of the paragraph "The use of a Copper Alloy surface is a supplement to and not a substitute for standard infection……."

> "The Copper Alloy surface material has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination."

3) On the second page of the proposed label, several parts of the Directions For Use are in brackets with the intent of possibly placing those parts on an insert. The brackets need to be removed. We believe that any time a pesticide claim is made on the label, the full directions for use need to be present since those directions are critical to the proper use of the product.

Please submit a revised labeling incorporating the above changes.

KELLEY DRYE
COLLIER SHANNON

Joseph J. Green
Of Counsel
Kelley Drye Collier Shannon
JGreen@KelleyDrye.com

February 26, 2008

Via Electronic Mail
Dennis J. Edwards, Branch Chief (7510C)
Regulatory Management Branch I
Antimicrobial Division, Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
edwards.dennis@epa.gov

Re: Antimicrobial Copper Alloys: Registration Conditions and Revised Label

Dear Dennis:

Following up on our February 26th meeting, on behalf of the Copper Development Association ("CDA"), we have developed proposed conditions for the registration of Antimicrobial Copper Alloys and a revised label that reflects the meeting discussions. We hope that the agency's prompt review of these materials will enable issuance of a final registration determination by the existing PRIA deadline of this Friday, February 29.

With regard to the Stewardship Plan discussed below, it is important to recognize that the Plan will be in place well in advance of product becoming available in the market. Even after obtaining EPA registration, alloy manufacturers will need at least three months to obtain "me too" registrations, then additional time will be needed to obtain the necessary state registrations. Accordingly, it will likely be at least six months after obtaining EPA registration that Antimicrobial Copper Alloy products will be delivered to the market. Therefore, implementation of the Plan will be well underway before the public (and infection control community) first starts seeing Antimicrobial Copper Alloys. However, as discussed during our meeting, obtaining federal registration is the critical first step in launching effective outreach efforts.

I. REGISTRATION CONDITIONS

We propose that the agency include as part of the registration the conditions described below.

Condition #1

Registrant will prepare and implement an Antimicrobial Copper Alloy Stewardship Plan ("the Plan") designed to support the responsible use of antimicrobial copper products. The Plan will be submitted for EPA review and approval within two months of the registration date. If EPA determines within 18

months of the registration date that the Plan is not being implemented, the registration may be terminated after notification to the Registrant and an opportunity to meet with the Director of the Office of Pesticide Programs.

The Plan will include, at a minimum, the following elements:

(a) Outreach to the infection control community, including:

(i) A goal of educating and reinforcing, for infection control professionals and other product users, the proper use of Antimicrobial Copper Alloys.

(ii) Written (including electronic) communications directed to associations of infection control professionals, such as APIC, ASHES, and any other relevant organizations identified by CDA or EPA, and State Departments of Health.

(iii) Initial outreach communications will be sent within six months and one year of registration, and then annually thereafter.

(iv) The content of the outreach communications will include statements explaining the registered claims and applications of Antimicrobial Copper Alloys, as well as their proper use. The communications also will inform the recipients about (1) the Antimicrobial Copper Alloy Working Group (see below) and invite their participation; (2) other sources of information on Antimicrobial Copper Alloys, including the Stewardship Website (see below). Additional content of outreach efforts will be developed as part of the Working Group activities.

(b) Development of a Stewardship Website ("the Website") under the auspices of the Copper Development Association ("CDA").

(i) The Website will serve as a resource for conveying accurate information to the public about the efficacy and proper use of Antimicrobial Copper Alloys.

(ii) The Website will include information on proper labeling and claims (including advertising); supporting science; applications; maintenance; and federal and state regulations.

(iii) A question and answer section will be developed to address common issues or questions raised with regard to Antimicrobial Copper Alloys.

(iv) The Website also will serve as a forum to correct any misleading third party statements or publications, including scientific papers, concerning Antimicrobial Copper Alloys.

(v) CDA will explore the possibility of linking the Stewardship Website to the websites of appropriate infection control organizations, such as APIC and ASHES.

(c) Establishment of an Antimicrobial Copper Alloy Working Group ("the Working Group").

(i) Invited participants will include alloy manufacturers, component makers, and representatives from the infection control community, including appropriate trade associations (*e.g.*, APIC and ASHES) and State Departments of Health.

(ii) The Working Group will meet at least twice a year, either in person or by live video conferencing (WEBEX) or teleconferencing.

(iii) The Working Group will serve as a forum to expand educational efforts, develop outreach communications, and address any questions or concerns from the public and infection control community.

Condition #2

For the first 18 months after registration, Registrant will submit to EPA sample advertising materials. Advertising materials will be representative of advertisements intended for use in the marketplace.

II. REVISED LABEL

Attached is a label revised to reflect our recent discussions. We have reformatted the label to help clarify for potential users the claims and directions for use.

In addition, we want to call your attention to two additional uses we have included on the list of applications: (1) grab handles on privacy curtains; and (2) lids for laundry hampers, trash canisters, and similar containers.

As discussed at our meeting, we believe that the proposed language is unnecessary regarding (1) the need to clean the products to remove tarnish, and (2) cross-contamination. Justifications for these conclusions are provided below.

A. Copper Alloys Do Not Need To Be Cleaned To Remove Tarnish Or Discoloration

From the draft label, we have removed proposed statements indicating the need to conduct routine cleaning to remove tarnish or discoloration. In contrast to dirt and grime, which prevent contact with the copper alloy surface, tarnish and discoloration are not a barrier to efficacy. Tarnish is primarily an oxidation reaction on the surface of the alloy and is comprised of copper oxide (a registered active ingredient). The tarnishing process begins immediately upon exposure of the alloy to air. Tarnished copper alloys, however, remain efficacious. This is supported not only by the GLP testing submitted in support of the registrations, but additional testing conducted by CDA.

The GLP testing was conducted over two years using copper alloy samples from the same production batches. Accordingly, these samples experienced normal tarnishing/oxidation over the several years from their production to their eventual use in testing. Prior to testing, these samples were cleaned to remove residual metalworking fluids that remained from the alloy production processes. The cleaning process did not involve rigorous scrubbing to remove any accumulated tarnish/oxidation on these aged surfaces. It was simply a cleaning process to remove residual oily residue on the alloy surfaces. The cleaned surfaces were not "bright" metallic surfaces and were not visibly different from the alloy surfaces prior to cleaning. The cleaned samples were utilized in testing within a range of several days to several weeks after cleaning. The GLP test data, therefore, reflect the performance of naturally tarnished copper alloys. In the next day or so, Doug Anderson of ATS Labs will provide Marcie Tidd (EPA Antimicrobial Division) with additional details on the GLP testing process and tarnishing of the samples used.

In addition, CDA conducted testing that demonstrates that tarnished alloys perform as well or better than non-tarnished ("bright") alloys. The attached chart shows the following performance of a "tarnished" and a "bright" sample for each of three copper alloys:

- C197 (99% Cu): 5 log drop on tarnished C197 in 60 minutes vs. no change on bright C197 in 60 minutes.
- C220 (90% Cu): 3 log drop on tarnished C220 in 60 minutes vs. no change on bright C220 in 60 minutes
- C770 (55% Cu): no difference between tarnished and bright C770 in 60 minutes (note: C770 is not among the alloys for which we are seeking registration).

For these reasons the statements regarding the need to clean tarnished alloys have been removed from the draft label.

B. <u>The Statement Regarding Cross-Contamination and Human Infection Is Unnecessary</u>

For several reasons, we struck the following statement from the draft label:

> "The surface material has been shown to inhibit microbial contamination but not necessarily to prevent cross contamination of microbes, nor to prevent human infection."

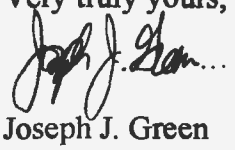
The GLP testing data show that copper alloys reduce, not just "inhibit," microbial contamination. Reduction of microbial contamination logically correlates to reducing the potential for cross-contamination of microbes. For this reason, other disinfectant products approved by EPA include label language that asserts that by reducing microbial contamination, the product helps prevent (or reduce the possibility of) cross-contamination. CDA is not seeking to make any statements regarding the efficacy of Antimicrobial Copper Alloys in reducing potential cross-contamination. However, it would be factually inaccurate, and contrary to established practice with regard to other antimicrobial products, to state that the alloys do not help reduce cross-contamination. Further, no product is allowed to state that it categorically prevents cross-contamination – or, conversely, that it does not do so. CDA should be held to the same standard.

Similarly, the statement that the product does not "prevent human infection" is unnecessary. No antimicrobial product can claim that it prevents infection – and, conversely, none are required to state that they do not. Human infection control is an FDA matter. The reference does not belong on the label.

* * * *

We look forward to your prompt response and final registration determination. Please let us know if you have any questions.

Very truly yours,



Joseph J. Green
Counsel to the Copper Development Association

APIC
ASSOCIATION FOR PROFESSIONALS IN
INFECTION CONTROL AND EPIDEMIOLOGY, INC.

1275 K Street NW, Suite 1000
Washington, DC 20005

Phone 202/789-1890
Fax 202/789-1899
apicinfo@apic.org
www.apic.org

February 25, 2008

Debbie Edwards, Ph.D.
Director
Office of Pesticides Programs
Environmental Protection Agency
Potomac Yard, South Tower
2777 Crystal Drive
Arlington, VA 22202

Dear Dr. Edwards:

As an international organization of over 11,000 infection prevention and control specialists, the Association for Professionals in Infection Control and Epidemiology (APIC) wishes to make you aware of its interest in Environmental Protection Agency (EPA) considerations of labeling antimicrobial products for use in health care settings.

As you know, pathogens are frequently present on environmental surfaces in healthcare settings. Further, these pathogens can survive for several days, making their spread from surface to humans a real possibility.

Antimicrobial products which have efficacy and are registered by the EPA to kill pathogens on environmental surfaces in healthcare settings could reduce exposure to, and transmission of, pathogens.

To some extent, as it applies to claims that the use of antimicrobial products can reduce exposure to pathogens and may improve adherence to cleaning and disinfecting regimens, these claims dovetail with APIC's "Targeting Zero" campaign. Through this worldwide effort, APIC members are targeting zero healthcare-associated infections (HAIs) in their institutions.

Thank you for your consideration of our comments. We look forward to working with you to ensure that labeling claims contribute to improved public health and are scientifically supportable.

Sincerely,

Kathy Warye
Chief Executive Officer

American Society for Healthcare Environmental Services

ASHES

Setting the Standard for Environmental Excellence™

TO: Environmental Protection Agency Antimicrobials Division in the Office of Pesticides Program

FROM: American Society for Healthcare Environmental Services
RE: Response to Request for Comments Regarding the Copper Institute Proposed Registration of Copper Alloys copper registrations and their role in infection control.

The Environmental Protection Agency Antimicrobials Division in the Office of Pesticides Program requested ASHES respond in writing to questions regarding an EPA registration application from the Copper Institute.

Our principal concern is an uniformed or misinformed user could potentially be misled to believe copper or copper alloy products provide a higher perceived value than real value in its effectiveness in preventing cross transmission or eradication of microorganisms in a healthcare setting. As such, ASHES has responded to the Agency's questions below.

1). Taking into account the proposed products/uses and associated label claims, would an infection control person alter their cleaning/sanitizing/disinfecting routine based on the proposed label claims? Would someone not take appropriate precautions due to a false sense of security? Could the claims be modified to eliminate/reduce this possibility?

ASHES Response:
In today's healthcare environment, there is heightened concern over the proliferation of various microorganisms; in particular, Methicillin-Resistant Staphyloccocus aureus, (MRSA) Vancomycin Resistant Enterococcus, (VRE) and Clostridium difficile, (C-diff). MRSA can survive in the hospital environment and on hospital surfaces and patients or workers can both transmit and/or acquire MRSA from contact with contaminated surfaces. Additionally, not only has it been proven that MRSA can survive on common healthcare surfaces, studies have indicated that patients can acquire MRSA from contact with those contaminated surfaces

In light of the information currently available from sound science and research, particularly as it relates to antibiotic resistant organisms, ASHES perspective on behalf of the healthcare environmental services profession is that the standard protocols and practices for environmental cleaning and disinfection would not be altered regardless of the product's label claim. Further, ASHES recommends following guidelines set forth by the Centers for Disease Control and Prevention(CDC):

- Guidelines for Environmental Infection Control in Health-Care Facilities
- CDC/HICPAC Isolation Guideline
- Multi Drug Resistant Organisms Guideline

2). These products are intended to be a supplement to conventional practices used in infection control. Do products such as the proposed copper registrations have a place in current infection control practices?

ASHES Response:
Our principal concern remains, that an uniformed or misinformed user could potentially be misled to believe copper or copper alloy products provide a higher perceived value than real value in its effectiveness in preventing cross transmission or eradication of microorganisms.

Additionally:

- The current national and international cost of copper and copper alloys has increased over 600% in the last five years. ASHES questions the cost benefit on healthcare construction and finish selection costs particularly since the standards protocols would not change based on existing Practice Guidance from ASHES, the CDC, and the Association for Practitioners in Infection Control and Epidemiology (APIC).

- Copper and alloys oxidize quickly and typically require more resources in the daily maintenance. How would construction professionals, architects and designers react to this aesthetically? Has research been conducted on how copper discoloration be prevented without altering the current label claim? Our impression is that the frontline workers maintaining the healthcare environment will have a workload increase and potentially result in higher costs for facilities implementing a similar program.

3). Are there other health care groups that we need to ask the same questions?

ASHES Response:
American Society for Healthcare Engineering (ASHE)

Questions/Responses Related to Pending Copper Alloy Registration Applications
APIC Public Policy and Practice Guidance Committees
December 20, 2007

Question:

Taking into account the proposed products/uses and associated label claims, would an infection control person alter their cleaning/sanitizing/disinfecting routine based on the proposed label claims?

Response:

APIC's committee representatives believe that qualified, competent Infection Control Professionals (ICP) would not alter their routine. However, there was concern an inexperienced ICP, new to the field could possibly do so. However, another committee member mentioned that ICPs are rarely responsible for daily cleaning/disinfection of the environment of care in their facilities. These activities are often carried out by environmental services and other personnel, such as nursing staff, nursing assistants, respiratory care, etc.

In addition, another committee member mentioned a product containing silver ions, which carries a claim against MRSA. This member believes that housekeepers may be cutting corners when they are very busy, in part because of the claims related to this product.

Finally, one member stated that, although ICPs would likely reinforce with appropriate personnel that they continue to perform routine cleaning/disinfecting activities, before integrating the type of products under consideration into objects or surfaces he would need to see data demonstrating an infection prevention benefit. There was agreement among the members on that point.

Question:

Would someone not take appropriate precautions due to a false sense of security?

Response:

Some committee members felt there was not much of a risk that ICPs would alter their practices. However, there was concern that other personnel might be susceptible to such a response due to the antimicrobial claim.

Question:

Could the claims be modified to eliminate/reduce this possibility?

Response:

Several members felt that the claim should be modified to reduce the possibility. In particular, there was a recommendation that the label be modified to state that "the surface material has been shown to inhibit microbial contamination, but not necessarily to prevent cross transmission of microbes, nor to prevent human infection."

Question:

These products are intended to be a supplement to conventional practices used in infection control. Do products such as the proposed copper registrations have a place in current infection control practices?

Response:

Although APIC committee members felt such products/approaches should be considered and researched, there was agreement that additional research was needed to provide evidence that a change to copper surfaces would decrease HAI rates. They stressed that this is not the same as proving that copper kills bacteria. In particular, APIC Committee Members stated that more applied research in natural settings such as hospitals is needed. Even with such research, they stressed that the primary mode of transmission of pathogens to patients in healthcare facilities remains via hands. Although the environment plays a role, to date there is very little evidence that incorporation of antimicrobials into surfaces around the patient significantly mitigates risk. However, there is emerging evidence that returning to basic interventions like attention to thorough cleaning is as important as any novel material. (SEE: Carling PC, et al. Identifying Opportunities to Enhance Environmental Cleaning in 23 Acute Care Hospitals. Infect Control Hosp Epidemiology 2008; 29:1-7.)

Finally, committee members felt it was important to point out that copper is a less attractive surface than stainless steel and is subject to significant corrosion.

Question:

Are there other health care groups that we need to ask the same questions?

Response:

Some recommended organizations and individuals to contact are as follows:

American Society for Healthcare Environmental Services (ASHES)
Of the American Hospital Association
Patti Costello

One North Franklin, Suite 2800, Chicago, IL 60606
312-422-3860
pcostello@aha.org

Scientists Actively Involved in the Use of Materials with Antimicrobial Properties, such as:

Dr. Michelle Alfa - Microbiology Laboratory, St. Boniface General Hospital, Winnipeg, MB, Canada. malfa@abgh.mb.ca

Dr. John M. Boyce - Hospital of Saint Raphael, New Haven, CT 06511, USA. JBoyce@srhs.org

Dr. William A. Rutala - Department of Hospital Epidemiology, University of North Carolina School of Medicine, Chapel Hill, NC 27599-7030, USA. brutala@unch.unc.edu

Dr. Syed Sattar - Centre for Research on Environmental Microbiology, Faculty of Medicine, University of Ottawa, Ottawa, ON, Canada [ssattar@uottawa.ca]

American Institute of Architect/Facility Guidelines Institute (AIA/FGI)
Doug S. Erickson, FASHE
Chair, Health Guidelines Steering Committee
Chair American Institute of Architects/Facility Guidelines Institute
ASHE Consultant on Codes and Standards
Cell: 847-347-0627
derick@bigplanet.com

The National Sanitation Foundation International (NSF) provides a considerable amount of laboratory testing for industry, in addition to a myriad of other services, involving certification of surfaces used in the food industry and likely elsewhere. Because of this extensive expertise they likely have scientists that can offer useful perspectives on incorporation of copper into high contact surfaces.

National Sanitation Foundation International
789 N. Dixboro Road
Ann Arbor, MI 48105 USA
Toll Free (USA): 800.NSF.MARK
Direct Phone: +1.734.769.8010
Fax: +1.734.769.0109
Email: info@nsf.org
Web: www.nsf.org

National Quality Forum (NQF)
601 13th Street NW, Suite 500 North
Washington DC 20005

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

09/27/07

DP BARCODE:	D335583
MRID:	469994-00, 471608-00, 469993-01, 471608-01, & 471608-02
SUBJECT:	ANTIMICROBIAL COPPER ALLOYS GROUP III^{+}
REG. NO. OR FILE SYMBOL:	82012-G
DOCUMENT TYPE:	Product Chemistry Review
Manufacturing-use [] OR	End-use Product [X]
INGREDIENTS (PC Codes)	Copper (022501)
CAS Number:	(7440-50-8)
TEST LAB:	None.
SUBMITTER:	Copper Development Association.
GUIDELINE:	830 Guidelines
COMMODITIES:	Formulation
REVIEWER:	Juan F. Negrón ORGANIZATION: AD
APPROVER:	Karen P. Hicks APPROVED DATE: 9/28/07
COMMENT:	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

09/27/07

TO:	Marshall Swindell / Karen Leavy PM Team 33
FROM:	Juan F. Negrón, Chemist Product Science Branch, CT Team Antimicrobial Division (7510P)
THRU:	Karen P. Hicks, CT Team Leader Product Science Branch Antimicrobial Division (7510P)
THRU:	Michele E. Wingfield, Chief Product Science Branch Antimicrobial Division (7510P)

APPLICANT: Copper Development Association
Action code: A50
Due date: 11/21/07

Product Formulation
Active Ingredient(s)

	% by wt.
Copper	82.6

BACKGROUND:

The registrant, Copper Development Association, is submitting a new product for registration. The integrated end-use product, ANTIMICROBIAL COPPER ALLOYS GROUP III^{+}, reduces bacterial contamination.

FINDINGS:

1. The Product Chemistry Reviewer has received the following documents:
   - Study titled "Antimicrobial Copper Alloys Group III." MRID # 469993-01.
   - Study titled "Antimicrobial Copper Alloys Group III." Group B MRID # 471608-01.
   - Study titled "Antimicrobial Copper Alloys Group III." Group A MRID # 471608-02.
   - Letters dated 12/01/06, 06/07/07, & 08/09/07.
   - Labels dated 12/05/06, & 06/20/07 (pin punch).
   - Confidential Statements of Formula (CSFs), dated 11/29/06, & 06/06/07, for the basic formulation.
   - Emails, dated 06/06/07, 06/12/07, & 08/09/07.
   - Preliminary analysis, dated 06/06/07. Volume 2 of 2.

2. The CSF, dated 11/29/06, for the basic formulation is obsolete.

3. The label, dated 12/05/06, is obsolete.

4. The CSF, dated 06/06/07, for the basic formulation is revised.

5. The registrant is requesting a waiver for storage stability and corrosive characteristic studies for an unregistered product because of the stability of the metal.

CONCLUSION:

The CSF, dated 06/06/07, for the basic formulation is acceptable. The Agency granted a waiver for storage stability and corrosive characteristic studies. The Product Chemistry package is acceptable. As per last meeting between the Agency and the registrant, Mr. Kerry Leifer reviewed the data and assigned a PC code (as of 09/25/07) for all elements that were not cleared. These elements are acceptable for nonfood use in antimicrobial formulations only.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system []
- Are all TGAIs used registered? Yes [ ] No [ ]
- Integrated formulation system [X]
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [] No [x]

c. Physical state of product: Solid

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.
Yes [X] No []

e. The NCs and CLs are acceptable. Yes [X] No [ ]

f. Active ingredient(s)

	NC (%)	LCL (%)	UCL (%)
Copper	82.6	75.8	89.6

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
Yes [ ] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
Yes [ ] No [ ] Not applicable [X]

Inert ingredient information may be entitled to confidential treatment

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [] No [X]

b. The formula contains one of the following:

[redacted]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [X] Not applicable []

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes [ ] No [x]

Table A:
Product Chemistry (830 Series, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	469993-01
830.1600 Description of Materials	A	469993-01
830.1620 Production Process[2]	A	469993-01
830.1650 Formulation Process[3]	A	469993-01
830.1670 Formation of Impurities[4]	A	469993-01
830.1700 Preliminary Analysis[5]	A	471608-02
830.1750 Certified Limits[6]	See CSF dated 06/06/07	
830.1800 Analytical Method[7]	A	469993-01
830.1900 Submittal of Samples	[Samples are to be provided upon request.]	469993-01

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

---

[1]See Confidential Appendix A for additional information
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	NR		
830.6303 Physical State	A	Solid.	471608-01
830.6304 Odor	NR	Not required for end-use products.	
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NR	Not required for end-use products.	
830.6314 Oxidation/Reduction; Chemical Incompatibility	A	No adverse reaction was observed.	471608-01
830.6315 Flammability/Flame Extension	A	Not flammable	471608-01
830.6316 Explodability	A	Not explosive.	471608-01
830.6317 Storage Stability	A	Requesting waiver since molecule is stable.	471608-01
830.6319 Miscibility[1]	A	The product is a metal that cannot be mixture with any fluid.	471608-01
830.6320 Corrosion Characteristics	A	The product is metal and no reaction will occur with the packaging material.	471608-01
830.6321 Dielectric Breakdown Voltage	A	Not to be used around electrical equipment.	471608-01
830.7000 pH[2]	A	Not miscible with water.	471608-01
830.7050 UV/Visible Absorption	NR	Not required for end-use products.	
830.7100 Viscosity	A	Product is a metal.	471608-01
830.7200 Melting Point/Melting Range	NR	Not required for end-use products.	
830.7220 Boiling Point/Boiling Range	NR	Not required for end-use products.	
830.7300 Density/Relative Density/Bulk Density	A	7.21 to 9.41 g/cm^3 .	471608-01
830.7370 Dissociation Constants in Water	NR	Not required for end-use products.	
830.7550/830.7560/830.7570 Partition Coefficient	NR	Not required for end-use products.	
830.7840/830.7860 Water Solubility	NR	Not required for end-use products.	
830.7950 Vapor Pressure	NR		

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

---

* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

January 10, 2008

DP BARCODE:	D348128
MRID:	472592-00, 472592-01
SUBJECT:	ANTIMICROBIAL COPPER ALLOYS GROUP III^{+}
REG. NO. OR FILE SYMBOL:	82012-G
DOCUMENT TYPE:	Product Chemistry Review
Manufacturing-use [] OR	End-use Product [X]
INGREDIENTS (PC Codes)	Copper (022501)
CAS Number:	(7440-50-8)
TEST LAB:	None.
SUBMITTER:	Copper Development Association.
GUIDELINE:	830.1550
COMMODITIES:	Formulation
REVIEWER:	Juan F. Negrón
ORGANIZATION:	AD
APPROVER:	Karen P. Hicks
APPROVED DATE:	1/10/08
COMMENT:	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

January 10, 2008

MEMORANDUM

Subject: Product Chemistry Review for EPA Reg # 82012-G.

From: Juan F. Negrón, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P)

Thru: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Marshall Swindell / Karen Leavy
PM Team 33

APPLICANT: Copper Development Association
Action code: 400
Due date: 01/21/08

Product Formulation
Active Ingredient(s)

	% by wt.
Copper	96.2

Inert ingredient information may be entitled to confidential treatment

BACKGROUND:

The registrant, Copper Development Association, is updating the 830.1550 guideline and the CSF for review. The registrant submitted an application for pesticide form, dated 10/17/07, in which indicated the purpose of the submission as "other." The registrant removed some components of the alloys such as [redacted] (see page 4 of the MRID #472592-01) that were in the previous CSF formulation. The integrated end-use product, ANTIMICROBIAL COPPER ALLOYS GROUP III^{+}, reduces bacterial contamination. The Product Chemistry Reviewer has received the following documents:

- A letter dated 10/17/08. MRID # 472592-00.
- Confidential Statement of Formula (CSF), dated 10/04/08, for the basic formulation.
- Study titled "Antimicrobial Copper Alloys Group III Product Properties – Group A" Volume 2 of 2. MRID #472592-01.
- Application for pesticide indicated as "other," dated 10/17/08.
- Data matrix dated 10/17/07.

FINDINGS:

1. The CSF, dated 10/04/08, for the basic formulation is revised.

2. The registrant removed the following component; [redacted]

CONCLUSION:

The CSF, dated 10/04/08, for the basic formulation is acceptable. These elements are acceptable for nonfood use in antimicrobial formulations only.

DATA PACKAGE BEAN SHEET

Date: 27-Sep-2007

Decision #: 372578

DP #: (335583)

PRIA

Parent DP#:

* * * Registration Information * * *

Registration: 82012-G - ANTIMICROBIAL COPPER ALLOYS - GROUP III

Company: 82012 - COPPER DEVELOPMENT ASSOCIATION (CDA)

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828

Risk Manager Reviewer: Karen Leavy KLEAVY

Sent Date: _____ Calculated Due Date: 21-Nov-2007 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A50) NEW USE;NON-FOOD;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 022501, Copper (metallic)(82.6%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 16-Jan-2007 Due Back: _____

DP Ingredient: 022501, Copper (metallic)

DP Title: _____

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #: _____

	Assigned To	Date In	Date Out	
Organization:	AD / PSB	16-Jan-2007		Last Possible Science Due Date: 01-Sep-2007
Team Name:	CTT	16-Jan-2007	13-Sep-2007	Science Due Date: 09-Jul-2007
Reviewer Name:	Negron, Juan	23-Jan-2007	13-Sep-2007	Sub Data Package Due Date: 24-Jul-2007
Contractor Name:				

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

Printed on Page 3

* * * Data Package Instructions * * *

Please review the product chemistry data(MRID# 469993-01) submitted in support of this application. PRIA, Action Code A50, Admin Due Date 9/22/07, CTT Due Date 4/22/07

46999301	Partially Acceptable	Brookman, D. (2006) Antimicrobial Copper Alloys Group III: Product Properties - Group A. Project Number: CDA/06/03. Unpublished study prepared by Technology Sciences Group, Inc. 36 p.	830.1550/Product Identity and composition
46999301	Partially Acceptable	Brookman, D. (2006) Antimicrobial Copper Alloys Group III: Product Properties - Group A. Project Number: CDA/06/03. Unpublished study prepared by Technology Sciences Group, Inc. 36 p.	830.1600/Description of materials used to produce the product
46999301	Partially Acceptable	Brookman, D. (2006) Antimicrobial Copper Alloys Group III: Product Properties - Group A. Project Number: CDA/06/03. Unpublished study prepared by Technology Sciences Group, Inc. 36 p.	830.1620/Description of production process
46999301	Partially Acceptable	Brookman, D. (2006) Antimicrobial Copper Alloys Group III: Product Properties - Group A. Project Number: CDA/06/03. Unpublished study prepared by Technology Sciences Group, Inc. 36 p.	830.1650/Description of formulation process
46999301	Partially Acceptable	Brookman, D. (2006) Antimicrobial Copper Alloys Group III: Product Properties - Group A. Project Number: CDA/06/03. Unpublished study prepared by Technology Sciences Group, Inc. 36 p.	830.1670/Discussion of formation of impurities
46999301	Partially Acceptable	Brookman, D. (2006) Antimicrobial Copper Alloys Group III: Product Properties - Group A. Project Number: CDA/06/03. Unpublished study prepared by Technology Sciences Group, Inc. 36 p.	830.1750/Certified limits
46999301	Partially Acceptable	Brookman, D. (2006) Antimicrobial Copper Alloys Group III: Product Properties - Group A. Project Number: CDA/06/03. Unpublished study prepared by Technology Sciences Group, Inc. 36 p.	830.1800/Enforcement analytical method
47160801	Acceptable	Brookman, D.; Moran, W. (2006) Antimicrobial Copper Alloys Group III: Product Properties -Group B. Project Number: CDA/06/08. Unpublished study prepared by Technology Sciences Group, Inc. 6 p.	111-222/
47160801	Acceptable	Brookman, D.; Moran, W. (2006) Antimicrobial Copper Alloys Group III: Product Properties -Group B. Project Number: CDA/06/08. Unpublished study prepared by Technology Sciences Group, Inc. 6 p.	830.6303/Physical state
47160801	Acceptable	Brookman, D.; Moran, W. (2006) Antimicrobial Copper Alloys Group III: Product Properties -Group B. Project Number: CDA/06/08. Unpublished study prepared by Technology Sciences Group, Inc. 6 p.	830.6314/Oxidizing or reducing action
47160801	Acceptable	Brookman, D.; Moran, W. (2006) Antimicrobial Copper Alloys Group III: Product Properties -Group B. Project Number: CDA/06/08. Unpublished study prepared by Technology Sciences Group, Inc. 6 p.	830.6315/Flammability
47160801	Acceptable	Brookman, D.; Moran, W. (2006) Antimicrobial Copper Alloys Group III: Product Properties -Group B. Project Number: CDA/06/08. Unpublished study prepared by Technology Sciences Group, Inc. 6 p.	830.6317/Storage stability of product
47160801	Acceptable	Brookman, D.; Moran, W. (2006) Antimicrobial Copper Alloys Group III: Product Properties -Group B. Project Number: CDA/06/08. Unpublished study prepared by Technology Sciences Group, Inc. 6 p.	830.6319/Miscibility
47160801	Acceptable	Brookman, D.; Moran, W. (2006) Antimicrobial Copper Alloys Group III: Product Properties -Group B. Project Number: CDA/06/08. Unpublished study prepared by Technology Sciences Group, Inc. 6 p.	830.6320/Corrosion characteristics
47160801	Acceptable	Brookman, D.; Moran, W. (2006) Antimicrobial Copper Alloys Group III: Product Properties -Group B. Project Number: CDA/06/08. Unpublished study prepared by Technology Sciences Group, Inc. 6 p.	830.6321/Dielectric breakdown voltage
47160801	Acceptable	Brookman, D.; Moran, W. (2006) Antimicrobial Copper Alloys Group III: Product Properties -Group B. Project Number: CDA/06/08. Unpublished study prepared by Technology Sciences Group, Inc. 6 p.	830.7000/pH of water solutions or suspensions
47160801	Acceptable	Brookman, D.; Moran, W. (2006) Antimicrobial Copper Alloys Group III: Product Properties -Group B. Project Number: CDA/06/08. Unpublished study prepared by Technology Sciences Group, Inc. 6 p.	830.7100/Viscosity
47160802	Acceptable	Brookman, D. (2007) Antimicrobial Copper Alloys Group III: Product Properties - Group A. Project Number: CDA/07/03. Unpublished study prepared by Technology Sciences Group, Inc. 8 p.	830.1700/Preliminary analysis

DP#: (335583) *** Additional Data Package for this Decision *** Decision#: (372578)

DP #	Division/Branch	Date Sent	Data Due	Instructions?	ICTF	Sent
335584	AD / RMB1	16-Jan-2007	01-Sep-2007	Yes No	Yes No	Yes No
335584	AD / RASSB	16-Jan-2007	01-Sep-2007	Yes No	Yes No	Yes No
335585	AD / RMB1	16-Jan-2007	09-Jul-2007	Yes No	Yes No	Yes No
335585	AD / PSB	16-Jan-2007	09-Jul-2007	Yes No	Yes No	Yes No

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Thursday, September 20, 2007

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. Nos.: 82012-R/ Group I
82012-E/ Group II
82012-G/ Group III
82012-U/ Group IV
82012-L/ Group V

DP Barcode: D342907, D342909, D342910, D342911, D342912

To: Marshall Swindell, PM 33/ Karen Leavy
Regulatory Management Branch
Antimicrobials Division (7510P)

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

Applicant: Copper Development Association (CDA)

1) BACKGROUND: The Copper Development Association requests waivers of the acute toxicity studies for their five new products based upon the composition and form of each product. The products are to be manufactured as doorknobs, doorplates and other solid objects. This waiver proposal is presented in the document:

Antimicrobial Copper Alloys Group I
Toxicology Data Waiver Requests 12/1/2006.
MRID Number 469996-03

2) RECOMMENDATIONS: PSB findings are:

a) The Chemistry and Toxicology Team (CTT) waives the requirements for the acute toxicity studies for these products. CTT consulted Risk Assessment and Science Support Branch (RASSB) toxicologists regarding the issue of the "inert" ingredients found in these five products. These scientists state that there should not be concern regarding any acute toxicity from these products.

b) This premise (above) that no acute toxicity studies are required for these products is based upon the following assumptions:

i) These products will all be marketed or found in the form of **large solid** products such as doorknobs and doorplates. As such, it will be virtually impossible to swallow, inhale or otherwise introduce one of these products into a human body.
ii) These products will not be granular, powdered, liquid or suspension in form. Should the physical form of any of these products be, or be changed to, granular, powdered, liquid or suspension, the requirements for acute toxicity studies of the subject product will have to be reevaluated.

c) One toxicologist did express concern that there may be surface residual materials of concern resulting from the "inerts" that may need to be assessed.

3) LABELING:

a) No precautionary labeling is required.

Note to PM Team 33:

Thursday, September 20, 2007

The Chemistry and Toxicology Team (CTT) consulted Drs. Steve Malish and Timothy McMahon on these unusual waiver requests.

Ian Blackwell

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

July 23, 2007

MEMORANDUM

Subject: Efficacy Review for Antimicrobial Copper Alloys – Group III and IV;
EPA Reg. No. 82012-G, DP Barcode 335585 (Group III); and
EPA Reg. No. 82012-U, DP Barcode 335592 (Group IV)

From: Lorilyn M. Montford LM
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Tajah Blackburn, Ph.D., Acting Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)
7/23/07

To: Marshall Swindell PM 33 / Karen Leavy
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Copper Development Association
260 Madison Avenue
New York, NY 10016

Formulation from the Label:

Active Ingredient(s)	% by wt.
Copper	82.6%
Other Ingredients	17.4%
Total	100.0%

I. BACKGROUND

The product, Antimicrobial Copper Alloys – Group III, is a new product (Registration Number 82012-G). **Note: Efficacy studies submitted for Group III are to be reviewed in support of Group IV Copper Alloys (Registration NO. 82012-U) as well.** Hence, Efficacy results for alloy C26000 (68.5% Cu) supports the registration for Groups III and IV. The product is intended for use in the manufacture of touch-surface products for hospital/medical, institutional, and commercial environments. Thirteen studies are being submitted to support claims for non-food bacteria reduction, residual bacteria reduction, and continual bacteria reduction. Protocols for this testing were previously submitted and found to be technically sound and acceptable for supporting specified label claims (see October 30, 2006 review by N. Whyte). The studies were conducted by ATS Labs, located at 1285 Corporate Center Drive, Suite 110 in Eagan, MN 55121.

The data package contained a data matrix, the proposed label, three copies of the summary of efficacy testing results, and 10 studies (MRID Numbers 469993-04 through 469993-13) with Statements of No Data Confidentiality and Good Laboratory Practice for all. A letter from the registrant was later provided to the Agency on 4/3/07 upon request by the product reviewer.

Note: The registrant only submitted 10 studies in support of the Copper Alloy Group III, not 11 as indicated on the data package bean sheet. The data package bean sheet lists MRID #469993-08 twice. The data submitted for Group III (MRID Nos. 469993-04 through 469993-13) is also intended to support Group IV as well.

II. USE DIRECTIONS

The product is intended for use in the manufacture of touch-surface products for hospital/medical, institutional, and commercial environments such as hospitals, medical offices, nursing homes, schools, athletic facilities, dwellings, lodgings, office buildings retail areas, and mass transit systems. The product may be used in the manufacture of such items as bedrails, bed-side tables, carts, water fountains, faucets, door handles, showerheads, toilet hardware, light switches, chair armrests and frames, floor tiles, knobs, IV poles, physical therapy equipment, elevators, soap dispensers, lockers, and outdoor playground equipment.

The proposed label lacks a section for directions for use. The label does mention that routine cleaning and sanitization of surfaces is required. "Cleaning agents typically used for traditional touching surfaces are permissible; the appropriate cleaning agent depends on the type of soiling and the measure of sanitization required." The surface must remain exposed and uncoated.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Sanitizer Test (for inanimate, non-food contact surfaces)

The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface over those on an untreated control surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes. These Agency standards are presented in DIS/TSS-10.

Supplemental Recommendations

Antimicrobial agents which claim to be "one-step" cleaner-disinfectants, or cleaner-sanitizers, or agents to be used in the presence of organic soil, must undergo appropriate efficacy testing modified to include a representative organic soil of 5% blood serum. A suggested method to simulate antimicrobial treatment of dry inanimate surfaces is to add the blood serum 5% v/v (19mL bacterial inoculum with 1mL blood serum) to bacterial inoculum prior to carrier contamination and drying. Control data should be produced as described in Supplemental Recommendation 6 of DIS/TSS-2 to confirm the validity of this test with this modification. The suggested organic soil level is appropriate for simulation of lightly to moderately soiled surfaces. For highly soiled surfaces, a prior cleaning step should be recommended on the product label. A suggested procedure for incorporating organic soil load where the antimicrobial agent is not tested against a dry inanimate surface, such as the AOAC Fungicidal Test involves adding 5% v/v blood serum directly to the test solution (e.g., 4.75 ml test solution + 0.25 ml blood serum) before adding 0.5 ml of the required level (5 X 10^6 /ml) of conidia. These agency standards can be found in DIS/TSS-2.

IV. SUMMARY OF SUBMITTED STUDIES

1. MRID 469993-05 "Test Method for the Continuous Reduction of Bacterial Contamination on Copper Alloy Surfaces" for Alloy C26000 by Jill Ruhme. Study conducted at ATS Labs, Project Number A03208. Study completed November 9, 2006.

This test was conducted against Methicillin Resistant *Staphylococcus aureus* (MRSA, ATCC 33592), *Escherichia coli* O157:H7 (ATCC 35150), and *Pseudomonas aeruginosa* (ATCC 15442) following ATS Labs protocol number CSC02032905.CUST.3H. Two lots (Lot Nos. 4237310 and 4237430) of alloy C26000 (a ready-to-use material) were tested. Fetal bovine serum was added to both cultures to create a 5% organic soil load supplemented with Triton X-100 (0.01%). Carriers consisted of 1" x 1" squares of the copper alloy test surface and 1" x 1" squares of stainless steel as a control surface. In preparation for the test, carriers were cleaned

with alcohol, rinsed with deionized water, and allowed to air dry. Carriers were flame sterilized prior to testing. Five sterile carriers were tested per material, per organism, per time point for a total of 150 test carriers and 30 control carriers. Exposure began at time zero when 5 µl of the 24-54 hour old cultures was spread over each of the carriers, which were dried at ambient conditions throughout the exposure period. Carrier sets not removed for quantitative recovery were reinoculated as described above at 3, 6, 9, 12, 15, 18, and 21 hours. At 2, 6, 12, 18, and 24 hours, sets of test and control carriers were removed for quantitative recovery and transferred to 20 ml of Letheen Broth each to neutralize. Each neutralizer/carrier tube was sonicated for 5 minutes to remove survivors and serially diluted within one hour. Dilutions were plated in duplicate on Tryptic Soy Agar with 5% Sheep Blood (BAP). Plates were incubated at 35-37C for 48±4 hours prior to observation. Following incubation, and storage, the plates were visually enumerated. Subcultures showing growth were subcultured, stained and/or biochemically assayed (unspecified assay type) to confirm presence or absence of the test organism. Controls included those for purity, sterility, viability, neutralization confirmation, and inoculum and carrier quantitation.

Note: The study indicates the following claim(s) are supported by this data:
"This surface continuously reduces bacterial* contamination."
"This surface provides continuous/ongoing/persistent antimicrobial action even with repeated exposures."
"This surface continuously kills over 90% of bacteria* after repeated exposures during a day."
"This surface prevents the buildup of disease-causing bacteria*."
"This surface delivers continuous, long-lasting antibacterial* activity."
*[Including Methicillin Resistant *Staphylococcus aureus* (MRSA, ATCC 33592), *Escherichia coli* O157:H7 (ATCC 35150), and *Pseudomonas aeruginosa* (ATCC 15442)]

2. MRID 469993-07 "Test Method for Efficacy of Copper Alloy Surfaces as a Sanitizer" for Alloy C26000 by Jill Ruhme. Study conducted by ATS Labs, Project Number A03318. Study completed November 7, 2006.

This test was conducted against Methicillin Resistant *Staphylococcus aureus* (MRSA, ATCC 33592), *Escherichia coli* O157:H7 (ATCC 35150), and *Pseudomonas aeruginosa* (ATCC 15442) following ATS Labs protocol number CSC02032905.CUST.1H. Two lots (Lot Nos. 4237310 and 4237430) of alloy C26000 (a ready-to-use material) were tested. Fetal bovine serum was added to both cultures to create a 5% organic soil load supplemented with Triton X-100 (0.01%). Carriers consisted of 1" x 1" squares of the copper alloy test surface and 1" x 1" squares of stainless steel as a control surface. In preparation for the test, carriers were cleaned, rinsed with deionized water, and allowed to air dry. Carriers were flame sterilized prior to testing. Five carriers were tested per material per organism. Each carrier was inoculated with a 0.02 ml aliquot of each 48±4 hour old culture and spread to within 1/8 inch of the carrier edges. Carriers were dried at room temperature for 20-40 minutes. Immediately following the drying period, the 120 minute exposure period began. Following exposure, carriers were transferred to 20 ml of neutralizer (Letheen Broth) and sonicated for 5 minutes to suspend cells from carriers. Serial dilutions (10^{-1}-10^{-4}) of the neutralized solutions were prepared and plated in duplicate on BAP plates (Tryptic Soy Agar with 5% sheep blood) using standard spread plate

technique. Plates were incubated at 35-37C for 48±4 hours prior to observation. Subculture plates were stored at 2-8C for two days prior to observation. Following incubation and storage, plates were visually enumerated. Cultures containing 30-300 colonies were used for calculations when possible. Controls included those for purity, sterility, viability, neutralization confirmation, inoculum count and carrier quantitation.

Note: There were no survivors reported on any of the copper test carriers.

Note: The study indicates the following claim(s) are supported by this data:
"This surface kills greater than 99.9% of bacteria* within two hours

3. MRID 469993-08 "Test Method for Residual Self-Sanitizing Activity of Copper Alloy Surfaces" for Alloy C26000 by Jill Ruhme. Study conducted by ATS Labs, Project Number A03425. Study completed November 7, 2006.

This test was conducted against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048) following ATS Labs protocol number CSC02032905.CUST.2G. Three lots (Lot Nos. 4237310, 4237430 and 4237450) of alloy C26000 (a ready-to-use material) were tested. Fetal bovine serum was added to both cultures to create a 5% organic soil load supplemented with Triton X-100 (0.01%). Carriers consisted of 1" x 1" squares of the copper alloy test surface and 1" x 1" squares of stainless steel as a control surface. In preparation for the test, carriers were cleaned with alcohol, rinsed thoroughly with deionized water, and allowed to air dry. Carriers were flame sterilized prior to testing. Five carriers were tested per material per organism per time point. Each carrier was inoculated with a 10 µL aliquot of each 48-54 hour old culture suspensions and spread to within 1/8 inch of the carrier edges. Carriers were dried at 35-37C for 30 minutes at a 38-42% relative humidity. Immediately following drying, the 120 minute exposure period began at ambient conditions. After this exposure period, carriers were transferred to 30 ml neutralizer (Letheen Broth) jars and sonicated for 20±2 seconds in a sonicating waterbath and mixed on an orbital shaker for 3-4 minutes at 250 rpm. Neutralized samples were serially diluted in sterile deionized water and plated in duplicate within one hour of neutralization. *S. aureus* plates were incubated at 35-37C and *E. aerogenes* plates were incubated at 25-30C for 48±4 hours prior to evaluation. Following incubation, plates were visually enumerated. Cultures containing 30-300 colonies were used for calculations when possible. After this initial inoculation, a series of 12 wear cycles with dry and moist cloths with reinoculation and drying between each were conducted. Each wear cycle consisted of one pass to the left and a return pass to the right on a Gardner scrubber with an abrasion boat fitted with a foam liner and dry or wet cotton cloth. 15 minutes after each wear cycle, carriers were reinoculated and dried for at least 30 minutes. Following the last wear cycle, a final inoculation was performed with a 120 minute contact time and recovered as in the initial inoculation. Controls included those for purity, sterility, viability, neutralization confirmation, and inoculum population.

Note: The study indicates the following claim(s) are supported by this data:
"This surface kills greater than 99.9% of bacteria* for 24 hours"
*[Including ***Staphylococcus*** *aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048)]

4. MRID 469993-09 "Test Method for Residual Self-Sanitizing Activity of Copper Alloy Surfaces" for Alloy C26000 by Jill Ruhme. Study conducted by ATS Labs, Project Number A03505. Study completed November 9, 2006.

This test was conducted against Methicillin Resistant *Staphylococcus aureus* (MRSA, ATCC 33592), *Escherichia coli* O157:H7 (ATCC 35150), and *Pseudomonas aeruginosa* (ATCC 15442) following ATS Labs protocol number CSC02032905.CUST.2H. Two lots (Lot Nos. 4237310 and 4237430) of alloy C26000 (a ready-to-use material) were tested. Fetal bovine serum was added to both cultures to create a 5% organic soil load supplemented with Triton X-100 (0.01%). Carriers consisted of 1" x 1" squares of the copper alloy test surface and 1" x 1" squares of stainless steel as a control surface. In preparation for the test, carriers were cleaned with alcohol, rinsed with deionized water, and allowed to air dry. Carriers were flame sterilized prior to testing. Four carriers were tested per material per organism per time point. Each carrier was inoculated with a 10 µL aliquot of each 48-54 hour old culture suspensions and spread to within 1/8 inch of the carrier edges. Carriers were dried at 35-37C for 30 minutes at a 38-42% relative humidity. Immediately following drying, the 120 minute exposure period began at ambient conditions. After this exposure period, carriers were transferred to 30 ml neutralizer (Letheen Broth) jars and sonicated for 20±2 seconds in a sonicating waterbath and mixed on an orbital shaker for 3-4 minutes at 250 rpm. Neutralized samples were serially diluted in sterile deionized water and plated in duplicate within one hour of neutralization. Plates were incubated at 35-37C for 48±4 hours prior to evaluation. Following incubation, plates were visually enumerated. Cultures containing 30-300 colonies were used for calculations when possible. After this initial inoculation, a series of 12 wear cycles with dry and moist cloths with reinoculation and drying between each were conducted. Each wear cycle consisted of one pass to the left and a return pass to the right on a Gardner scrubber with an abrasion boat fitted with a foam liner and dry or wet cotton cloth. 15 minutes after each wear cycle, carriers were reinoculated and dried for at least 30 minutes. Following the last wear cycle, a final inoculation was performed with a 120 minute contact time and recovered as in the initial inoculation. Controls included those for purity, sterility, viability, neutralization confirmation, and inoculum population.

Note: The study indicates the following claim(s) are supported by this data:
"This surface kills greater than 99.9% of bacteria* for 24 hours"
*[Including Methicillin Resistant *Staphylococcus aureus* (MRSA, ATCC 33592), *Escherichia coli* O157:H7 (ATCC 35150), and *Pseudomonas aeruginosa* (ATCC 15442)]

5. MRID 469993-12 "Test Method for Efficacy of Copper Alloy Surfaces as a Sanitizer" for Alloy C26000 by Amy S. Jeske. Study conducted by ATS Labs, Project Number A03844. Study completed November 6, 2006.

This test was conducted against *Staphylococcus aureus (*ATCC 6538) and *Enterobacter aerogenes (*ATCC 13048) following ATS Labs protocol number CSC02040406.CUST.1B (copy later provided upon request). Three lots (Lot Nos. 4237310, 4237430, and 4237450) of alloy C26000 (a ready-to-use material) were tested. Fetal bovine serum was added to both cultures to create a 5% organic soil load supplemented with Triton X-100 (0.01%). Carriers consisted of 1" x 1" squares of the copper alloy test surface and 1" x 1" squares of stainless steel as a

control surface. In preparation for the test, carriers were cleaned (following ATS SOP CGT-4340C, "Preparation of Carriers for Use in Testing"), rinsed with deionized water, and allowed to air dry. Carriers were flame sterilized prior to testing. Five carriers were tested per material per organism. Each carrier was inoculated with a 0.02 ml aliquot of each 48±4 hour old culture and spread to within 1/8 inch of the carrier edges. Carriers were dried at room temperature for 20-40 minutes. Immediately following the drying period, the 120 minute exposure period began. Following exposure, carriers were transferred to 20 ml of neutralizer (Letheen Broth) and sonicated for 5 minutes to suspend cells from carriers. Serial dilutions (10^{-1}-10^{-4}) of the neutralized solutions were prepared and plated in duplicate on BAP plates (Tryptic Soy Agar with 5% sheep blood) using standard spread plate technique. *S. aureus* plates were incubated at 35-37C for 48±4 hours prior to observation. *E. aerogenes* plates were incubated at 25-30C for 48±4 hours prior to observation. Following incubation, plates were visually enumerated. Cultures containing 30-300 colonies were used for calculations when possible. Controls included those for purity, sterility, viability, neutralization confirmation, inoculum count and carrier quantitation.

Note: There were no survivors reported on any of the copper test carriers.

Note: The study indicates the following claim(s) are supported by this data:
"This surface kills greater than 99.9% of bacteria* within two hours"
*[Including *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048)]

6. MRID 469993-13 "Test Method for the Continuous Reduction of Bacterial Contamination on Copper Alloy Surfaces" for Alloy C26000 by Amy S. Jeske. Study conducted at ATS Labs, Project Number A03845. Study completed November 6, 2006.

This test was conducted against *Staphylococcus aureus* ATCC 6538 and *Enterobacter aerogenes* ATCC 13048 following ATS Labs protocol number CSC02040406.CUST.3A. Three lots (Lot Nos. 4237310, 4237430 and 4237450) of alloy C75200 (a ready-to-use material) were tested. Fetal bovine serum was added to both cultures to create a 5% organic soil load supplemented with Triton X-100 (0.01%). Carriers consisted of 1" x 1" squares of the copper alloy test surface and 1" x 1" squares of stainless steel as a control surface. In preparation for the test, carriers were cleaned with alcohol, rinsed with deionized water, and allowed to air dry. Carriers were flame sterilized prior to testing. Five sterile carriers were tested per material, per organism, per time point for a total of 150 test carriers and 30 control carriers. Exposure began at time zero when 5 µl of the 24-54 hour old cultures was spread over each of the carriers, which were dried at ambient conditions throughout the exposure period. Carrier sets not removed for quantitative recovery were reinoculated as described above at 3, 6, 9, 12, 15, 18, and 21 hours. At 2, 6, 12, 18, and 24 hours, sets of test and control carriers were removed for quantitative recovery and transferred to 20 ml of Letheen Broth each to neutralize. Each neutralizer/carrier tube was sonicated for 5 minutes to remove survivors and serially diluted within one hour. Dilutions were plated in duplicate on Tryptic Soy Agar with 5% Sheep Blood (BAP). *S. aureus* plates were incubated at 35-37C for 48±4 hours prior to observation and *E. aerogenes* plates were incubated at 25-30C for 48±4 hours. Subcultures were stored at 2-8C for two days prior to examination. Following incubation and storage, plates were visually enumerated. Subcultures showing growth were subcultured, stained and/or biochemically

assayed (unspecified assay type) to confirm presence or absence of the test organism. Controls included those for purity, sterility, viability, neutralization confirmation, and inoculum and carrier quantitation.

Note: The study indicates the following claim(s) are supported by this data:
"This surface continuously reduces bacterial* contamination."
"This surface provides continuous/ongoing/persistent antimicrobial action even with repeated exposures."
"This surface continuously kills over 90% of bacteria* after repeated exposures during a day."
"This surface prevents the buildup of disease-causing bacteria*."
"This surface delivers continuous, long-lasting antibacterial* activity."
*[Including *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048)]

7. The following additional studies were also submitted but not reviewed, as they were conducted as part of the protocol development process and are not intended to support product registration (per June 7, 2007 letter from the applicant's representative).

MRID	Method	Organisms
469993-06	Bacteria Reduction	*S. aureus, E. aerogenes*
469993-10	Bacteria Reduction	*S. aureus, E. aerogenes*
469993-11	Continuous Reduction	MRSA, *E. coli* O157:H7, *P. aeruginosa*
469993-04	Continuous Reduction	*S. aureus, E. aerogenes*

V. RESULTS

MRID	Organism	Inoculum Count (CFU/mL)	Steel Carrier Control (mean CFU/ Carrier)	Results (Mean Survivors/Carrier)			Percent Reduction over Steel Control
				Lot 4237310	Lot 4237430	Lot 4237450	
469993-12	*S. aureus*	5.6×10^8	3.02×10^6	$<2.00 \times 10^2$	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
	E. aerogenes	1.38×10^9	1.86×10^7	$<2.00 \times 10^2$	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
469993-07	MRSA	6.9×10^8	4.57×10^6	$<2.00 \times 10^2$	$<2.00 \times 10^2$		>99.9
	E. coli O157:H7	8.9×10^8	2.19×10^5	$<2.00 \times 10^2$	$<2.00 \times 10^2$		>99.9
	P. aeruginosa	7.9×10^9	2.34×10^6	$<2.00 \times 10^2$	$<2.00 \times 10^2$		>99.9

MRID	Organism		Steel Carrier Control (mean CFU/ Carrier)	Results (Mean Survivors/Carrier)			Minimum Percent Reduction over Steel Control
				Lot 4237310	Lot 4237430	Lot 4237450	
469993-08	*S. aureus*	Initial	4.68×10^5	$<1.02 \times 10^2$	$<4.90 \times 10^1$	$<3.98 \times 10^1$	>99.9
		Final	3.63×10^5	$<7.24 \times 10^1$	$<7.08 \times 10^1$	$<5.37 \times 10^1$	>99.9
	E. aerogenes	Initial	2.40×10^8	$<3.02 \times 10^1$	$<1.02 \times 10^1$	$<3.02 \times 10^1$	>99.9
		Final	5.89×10^6	$<3.02 \times 10^1$	$<3.02 \times 10^1$	$<3.02 \times 10^1$	>99.9
				-	-	-	-
469993-09	MRSA	Initial	7.24×10^5	$<3.02 \times 10^1$	$<3.02 \times 10^1$	-	>99.9
		Final	4.68×10^5	$<3.02 \times 10^1$	$<3.02 \times 10^1$		>99.9
	E. coli O157:H7	Initial	1.12×10^5	$<3.02 \times 10^1$	$<3.02 \times 10^1$	-	>99.9
		Final	9.1×10^4	$<3.02 \times 10^1$	$<3.02 \times 10^1$		>99.9
	P. aeruginosa	Initial	2.45×10^6	$<3.02 \times 10^1$	$<3.02 \times 10^1$	-	>99.9
		Final	2.69×10^8	$<3.02 \times 10^1$	$<3.02 \times 10^1$		>99.9

MRID	Organism	Exposure Time (Hours)	Steel Carrier Control (mean CFU/ Carrier)	Results (Mean Survivors/Carrier)			Minimum Percent Reduction over Steel Control
				Lot 4237310	Lot 4237430	Lot 4237450	
469993 -13	*S. aureus*	2	3.72×10^5	$<2.00 \times 10^2$	$<2.75 \times 10^2$	$<2.00 \times 10^2$	>99.9
		6	6.61×10^5	$<2.88 \times 10^2$	$<3.31 \times 10^2$	$<2.00 \times 10^2$	>99.9
		12	1.86×10^5	$<1.78 \times 10^2$	$<1.51 \times 10^4$	$<1.32 \times 10^4$	>99.2
		18	3.09×10^6	$<2.34 \times 10^4$	$<2.34 \times 10^4$	1.95×10^4	>99.9
		24	5.13×10^6	1.38×10^4	1.38×10^4	1.51×10^4	>99.9
	E. aerogenes	2	1.55×10^7	$<2.00 \times 10^2$	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
		6	1.51×10^7	$<2.00 \times 10^2$	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
		12	8.13×10^6	$<2.00 \times 10^2$	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
		18	6.31×10^6	$<2.00 \times 10^2$	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
		24	2.19×10^7	$<6.92 \times 10^2$	$<2.29 \times 10^2$	$<2.29 \times 10^2$	>99.9
469993 -05	MRSA	2	6.61×10^5	$<2.00 \times 10^2$	$<2.00 \times 10^2$	-	>99.9
		6	1.74×10^6	$<2.00 \times 10^2$	$<2.00 \times 10^2$	-	>99.9
		12	3.39×10^6	6.31×10^2	$<5.62 \times 10^2$	-	>99.9
		18	1.07×10^7	3.98×10^3	6.61×10^2	-	>99.9
		24	6.61×10^7	1.00×10^4	7.08×10^2	-	>99.9
	E. coli O157:H7	2	1.12×10^5	$<2.00 \times 10^2$	$<2.00 \times 10^2$	-	>99.9
		6	9.33×10^4	$<2.00 \times 10^2$	$<2.00 \times 10^2$	-	>99.9
		12	1.00×10^5	$<2.00 \times 10^2$	$<2.00 \times 10^2$	-	>99.9
		18	1.66×10^5	$<2.00 \times 10^2$	$<2.00 \times 10^2$	-	>99.9
		24	5.01×10^5	$<2.00 \times 10^2$	$<2.00 \times 10^2$	-	>99.9
	P. aeruginosa	2	1.78×10^6	$<2.00 \times 10^2$	$<2.00 \times 10^2$	-	>99.9
		6	1.78×10^6	$<2.00 \times 10^2$	$<2.00 \times 10^2$	-	>99.9
		12	2.00×10^6	$<2.00 \times 10^2$	$<2.00 \times 10^2$	-	>99.9
		18	2.57×10^6	$<2.00 \times 10^2$	$<2.00 \times 10^2$	-	>99.9
		24	6.17×10^6	$<2.00 \times 10^2$	$<2.00 \times 10^2$	-	>99.9

VI. CONCLUSIONS

1. The submitted efficacy data (MRID 469993-12) supports the use of the product, Alloy C26000, Copper Groups III and IV. The product reduces 99.9% of bacteria against *Staphylococcus aureus* and *Enterobacter aerogenes* on hard, non-porous surfaces in the presence of a 5% fetal bovine serum and 0.01% Triton X-100 organic soil load for a contact time of 120 minutes.

2. The submitted efficacy data (MRID # 469993-07) supports the use of the product, Alloy C26000, Copper Groups III and IV. The product reduces 99.9% of bacteria against Methicillin Resistant *Staphylococcus aureus* (MRSA), *Escherichia coli*, and *Pseudomonas aeruginosa* on hard, non-porous surfaces in the presence of a 5% fetal

bovine serum and 0.01% Triton X-100 organic soil load for a contact time of 120 minute exposure period.

3. The submitted efficacy data (MRID #469993-08) supports the use of the product, Alloy C26000, Copper Groups III and IV. The product reduces 99.9% of bacteria demonstrating residual self sanitizing against *Staphylococcus aureus* and *Enterobacter aerogenes* in the presence of a 5% fetal bovine serum and 0.01% Triton X-100 organic soil load for a contact time of 120 minute exposure period.

4. The submitted efficacy data (MRID #469993-09) supports the use of the product, Alloy C26000, Copper Groups III and IV. The product reduces 99.9% of bacteria demonstrating residual self sanitizing against Methicillin Resistant *Staphylococcus aureus* (MRSA), *Escherichia coli* and *Pseudomonas aeruginosa* in the presence of a 5% fetal bovine serum and 0.01% Triton X-100 organic soil load for a contact time of 120 minute exposure period.

5. The submitted efficacy data (MRID #469993-013) supports the use of the product, Alloy C26000, Copper Groups III and IV. The product continuously reduces 99% of the bacteria demonstrating Continuous Reduction of bacterial contamination against *Staphylococcus aureus* and *Enterobacter aerogenes* in the presence of a 5% fetal bovine serum and 0.01% Triton X-100 organic soil load for an exposure period of 2 to 24 hours.

6. The submitted efficacy data (MRID #469993-05) supports the use of the product, Alloy C26000, Copper Groups III and IV. The product continuously reduces 99% of the bacteria demonstrating Continuous Reduction of bacterial contamination against Methicillin Resistant *Staphylococcus aureus* (MRSA), *Escherichia coli* and *Pseudomonas aeruginosa* in the presence of a 5% fetal bovine serum and 0.01% Triton X-100 organic soil load for an exposure period of 2 to 24 hours.

VII. RECOMMENDATIONS

1. The proposed label claims that the product, Copper Alloy C26000 (Groups III and IV) is an effective sanitizer against the following for a contact time of 120 minute exposure period demonstrating residual self sanitization, and for a contact time over a 2 to 24 hour exposure period demonstrating continuous reduction of bacterial contamination on hard non-porous surfaces in the presence of a 5% fetal bovine serum and 0.01% Triton X-100 organic soil load:

    -Methicillin Resistant *Staphylococcus aureus* (MRSA) (ATCC 33592)
    -*Escherichia coli* (ATCC 35150)
    -*Enterobacter aerogenes* (ATCC 13048)
    -*Pseudomonas aeruginosa* (ATCC 15442)
    -*Staphylococcus aureus* (ATCC 6538)

    The data support these claims.

2. Making the following changes would improve the label:

Initial Cleaning Directions and Maintenance Directions

In review of the submitted efficacy studies, it is apparent that cleaning is required to elicit and maintain 3-log reduction in efficacy. An initial cleaning or "degreasing step" should be included on the label to address removal or residual manufacturing oil and debris. This initial cleaning step will be reserved for newly incorporated surfaces and sites. For claims of continuous, long-lasting activity and residual activity, a maintenance cleaning step should be included on the proposed label. The language for this maintenance cleaning step should indicate that high touch surfaces with significant bioload should be subjected to daily cleaning to elicit continued efficacy, as demonstrated in the test systems. As an extension of label cleaning verbiage, agents compatible with the copper surfaces should be included.

"Practical" surfaces can remain on the label, when acceptable cleaning directions are provided

Surfaces to be Removed from the Label

--Remove all outdoor surfaces from the label (playground equipment) as the efficacy test performed does not adequately represent conditions the surfaces would be exposed to in an outdoor environment.

-- Remove all textiles (uniforms, curtains, sheets, pillow cases), as these are porous surfaces for which efficacy has not been demonstrated.

-- Remove shopping cart handles and child seats from the proposed label. These surfaces are extremely high-touch surfaces, unlikely to be cleaned every 24 hours. Furthermore these surfaces are likely to be left outside for extended periods.

--The following surfaces are "high-touch" surfaces with significant bioload that aren't practical to clean on a consistent basis (efficacy may not be demonstrated if cleaning is not performed on a daily/routine basis). Daily cleaning is mandatory for high-touch surfaces that may undergo frequent re-colonization. Please remove the following surfaces from the label.

Healthcare Facilities
Bedrails, footboards
Bedrails, assistance rails
Paper towel holders
Alcohol sanitizer dispenser handles
Showerheads
Visitor chairs, armrest, metal frames
Closures
Vertical locking arms
Vertical cover guards
Protection bars
Thermostat covers
Telephone handsets and surfaces (housings) keyboards

Ceiling tiles (request additional information, regarding types, often these are porous)
Walkers, wheelchair handles, and tubular components
Computer keyboards: keys, housings, computer mouse
Medical records: chart holders, clipboards, filing systems
Storage shelving: wire shelving etc. for medical supplies

Community Facilities

Cash registers: housing, keypads
ATM machines: keys, housing (must be indoor)
Gym/Health club lockers, locker handles locker shelving, trainers' tables
Ice and water dispensers (outer surfaces without water contact)
Windows (crank), Locking mechanism, pull handles
Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
Jalousie Windows (crank)
Casement (cranks, levers, hinges)
Single and double-hung windows (locks and pulls)

3. On page 5 of the proposed label (mid-way through the list of use surfaces), add non-food contact only in parenthesis next to "countertops and tabletops".

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

12/4/07

MEMORANDUM

SUBJECT: **Metallic Copper Alloys (P.C. Code 022501). Copper Alloy Products.** PRIA submission to conduct a toxicology assessment of five groups of copper alloys proposed to be made into objects possessing antimicrobial activity. DP Barcode/EPA Reg. No.: D346663/82012-E; D346665/82012-E; D346666/82012-E; D346667/82012-E; and D346668/82012-E.

FROM: William J. Hazel, Ph.D., Chemist
and
Jonathan Chen, Ph.D., Toxicologist
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

THROUGH: Norman Cook, Branch Chief
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

TO: Karen Leavy-Munk, Team 33
Regulatory Management Branch I
Antimicrobials Division (7510P)

INTRODUCTION:

The Copper Development Association, Inc. (CDA), a group of copper producers, brass mills, wire and cable companies, foundries, etc., has proposed to register five Antimicrobial Copper Alloys Groups comprised of 275 metallic copper alloys for which an antimicrobial claim has been made. These alloys will be shaped into objects that are frequently touched by human hands (touch surfaces) such as doorknobs, bed railings, IV poles, handles, knobs, etc. in health care facilities, community facilities, residential facilities, and limited playground equipment. Each alloy will be comprised of a commercial copper source (the active

ingredient) and at least one other element (an intentionally-added inert) depending on the object and disposition thereof. The actual active antimicrobial chemical species is the copper ion (largely Cu^{+2}) which would form gradually on the surface of the object constructed of the copper alloy depending on the environmental conditions. The inerts are generally metals that are added to impart certain properties to a given copper alloy such as strength, color, or corrosion resistance.

BACKGROUND:

Several communications, via teleconference or meeting, took place between CDA and EPA between April, 2004 and 4/18/07; the latter was a presentation of the antimicrobial properties of the copper alloys. The formal application for registration of the Antimicrobial Copper Alloys Groups I-V, dated 12/1/06, was made by Kelly Drye Collier Shannon on behalf of the CDA; at that time, there were a total of 317 different alloys. However, based partially on Agency concern over inerts of potential risk such as [redacted], this number of alloys was reduced to 275 when the Confidential Statements of Formula (CSFs) were revised on 10/4/07.

PROPOSAL:

The Agency has already agreed, in principle, that consideration for membership in one of the Antimicrobial Copper Alloy Groups would be given to all of the metallic copper alloys for which the CDA seeks registration. Membership in a specific Alloy Group is based on the percent by weight of copper in the alloy. The 10/4/07 CSFs break out as follows:

Group I contains 137 alloys at a nominal concentration of 96.2% Cu
Group II contains 54 alloys at a nominal concentration of 91.3% Cu
Group III contains 48 alloys at a nominal concentration of 82.6% Cu
Group IV contains 28 alloys at a nominal concentration of 73.0% Cu
Group V contains 8 alloys at a nominal concentration of 66.5% Cu

The 10/4/07 CSFs reflected removal of [redacted] from all Copper Alloy Groups and removal of [redacted] from Group II. The only remaining inerts of potentially toxic concern are [redacted] in Copper Alloys Group II and, in Group I, [redacted] CDA is planning to propose registration of a group of Antimicrobial Copper Alloys containing [redacted] at a later date.

CDA has made the following label claims: each alloy kills >99.9% of G^+ and G^- bacteria within 2 hr; each alloy kills >99.9% of G^+ and G^- bacteria over a 2-hr period; each alloy continuously kills >99% of G^+ and G^- bacteria over a 24-hr

period; and each alloy kills >99% of G^+ and G^- bacteria after repeated contamination over a 24-hr period. AD has reviewed CDA's efficacy studies generated on representative alloys from the five groups. There are still a number of issues remaining to be resolved between the AD and CDA regarding efficacy and labeling and between AD and OGC.

CONCLUSIONS:

The Agency has no concern over the major component of the five pending Antimicrobial Copper Alloy Groups, i.e., the metallic copper. The copper in the alloys is present in the metallic form which is essentially immobile and nontoxic in that form. The actual antimicrobial active ingredients are largely copper ions which would form gradually and only on the surface of the object constructed of the copper alloy depending on the environmental conditions. Although food uses are not being sought at this time, there are many registered agricultural, aquatic, and antifoulant uses of copper compounds that have resulted in concomitant exemptions from the requirement of a tolerance (40 CFR 180.1021). The major bases for the exemptions are that copper is an essential element, that the human body has controls over copper homeostasis to prevent high or low endogenous levels, and that no adverse systemic effects have been associated with copper compounds at any dose, including those high enough to cause gastric irritation. Similarly, adverse systemic effects are not induced via the dermal route of exposure to copper compounds and a few copper salts caused only very mild dermal irritation (Copper RED. 1/17/06. Joint HED/AD Human Health Assessment. D319683).

In terms of the many inert ingredients likely to be intentionally-added to make the various alloys, just as in the case of copper, each is present in the neutral, uncharged, or metallic form. Major ones may be [redacted]. The vast majority of the atoms of these elements will remain forever unexposed to the elements and untouched by human hands. Only small amounts of cations (positively charged ions) of these neutral metals will form, and, again, these will form only on the surface. Regardless, the major intentionally-added inerts in the proposed products are not of human health concern to the Agency.

Regarding potentially toxic inert ingredients, the Agency no longer has a concern for any ingredient in File Symbols 82012-G (Antimicrobial Copper Alloys Group III), 82012-U (Group IV), and 82012-L (Group V) as CDA voluntarily removed [redacted] from all alloys in these groups (and groups I and II as well).

Based on the 10/4/07 CSFs, [redacted] that could potentially be of concern to the Agency. These inerts of potential concern only apply to File Symbols 82012-R (Group I) and 82012-E (Group II): [redacted]

[redacted]

Humans have been exposed to numerous copper products and copper alloy touch surfaces for hundreds of years. All of these products included other metals as impurities and/or as alloying metals; in many cases, these products would have been fabricated long before we were aware of the toxicity of the cationic forms of some of the component metals. The Agency is certain that many of these older copper alloy products remain in use and that newer ones are being made [just without an antimicrobial claim.]

The bottom line is that many humans are likely to be currently exposed to the same neutral/metallic forms and ionic forms of the copper and intentionally-added inerts used to formulate the 275 copper alloys as we would be exposed to via our food, drinking water, existing touch surfaces, and any number of other exposure sources. The additional exposure of humans to the two or three potentially toxic inerts from use of Antimicrobial Copper Alloy Products is expected to be negligible.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

12/4/07

MEMORANDUM

SUBJECT: **Metallic Copper Alloys (P.C. Code 022501). Copper Alloy Products.** PRIA submission to conduct a toxicology assessment of five groups of copper alloys proposed to be made into objects possessing antimicrobial activity. DP Barcode/EPA Reg. No.: D346663/82012-E; D346665/82012-E; D346666/82012-E; D346667/82012-E; and D346668/82012-E.

FROM: William J. Hazel, Ph.D., Chemist
and
Jonathan Chen, Ph.D., Toxicologist
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

THROUGH: Norman Cook, Branch Chief
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

TO: Karen Leavy-Munk, Team 33
Regulatory Management Branch I
Antimicrobials Division (7510P)

INTRODUCTION:

The Copper Development Association, Inc. (CDA), a group of copper producers, brass mills, wire and cable companies, foundries, etc., has proposed to register five Antimicrobial Copper Alloys Groups comprised of 275 metallic copper alloys for which an antimicrobial claim has been made. These alloys will be shaped into objects that are frequently touched by human hands (touch surfaces) such as doorknobs, bed railings, IV poles, handles, knobs, etc. in health care facilities, community facilities, residential facilities, and limited playground equipment. Each alloy will be comprised of a commercial copper source (the active

ingredient) and at least one other element (an intentionally-added inert) depending on the object and disposition thereof. The actual active antimicrobial chemical species is the copper ion (largely Cu^{+2}) which would form gradually on the surface of the object constructed of the copper alloy depending on the environmental conditions. The inerts are generally metals that are added to impart certain properties to a given copper alloy such as strength, color, or corrosion resistance.

BACKGROUND:

Several communications, via teleconference or meeting, took place between CDA and EPA between April, 2004 and 4/18/07; the latter was a presentation of the antimicrobial properties of the copper alloys. The formal application for registration of the Antimicrobial Copper Alloys Groups I-V, dated 12/1/06, was made by Kelly Drye Collier Shannon on behalf of the CDA; at that time, there were a total of 317 different alloys. However, based partially on Agency concern over inerts of potential risk such as [redacted], this number of alloys was reduced to 275 when the Confidential Statements of Formula (CSFs) were revised on 10/4/07.

PROPOSAL:

The Agency has already agreed, in principle, that consideration for membership in one of the Antimicrobial Copper Alloy Groups would be given to all of the metallic copper alloys for which the CDA seeks registration. Membership in a specific Alloy Group is based on the percent by weight of copper in the alloy. The 10/4/07 CSFs break out as follows:

Group I contains 137 alloys at a nominal concentration of 96.2% Cu
Group II contains 54 alloys at a nominal concentration of 91.3% Cu
Group III contains 48 alloys at a nominal concentration of 82.6% Cu
Group IV contains 28 alloys at a nominal concentration of 73.0% Cu
Group V contains 8 alloys at a nominal concentration of 66.5% Cu

The 10/4/07 CSFs reflected removal of [redacted] from all Copper Alloy Groups and removal of [redacted] from Group II. The only remaining inerts of potentially toxic concern are [redacted] in Copper Alloys Group II and, in Group I, [redacted] CDA is planning to propose registration of a group of Antimicrobial Copper Alloys containing [redacted] at a later date.

CDA has made the following label claims: each alloy kills >99.9% of G^+ and G^- bacteria within 2 hr; each alloy kills >99.9% of G^+ and G^- bacteria over a 2-hr period; each alloy continuously kills >99% of G^+ and G^- bacteria over a 24-hr

period; and each alloy kills >99% of G^+ and G^- bacteria after repeated contamination over a 24-hr period. AD has reviewed CDA's efficacy studies generated on representative alloys from the five groups. There are still a number of issues remaining to be resolved between the AD and CDA regarding efficacy and labeling and between AD and OGC.

CONCLUSIONS:

The Agency has no concern over the major component of the five pending Antimicrobial Copper Alloy Groups, i.e., the metallic copper. The copper in the alloys is present in the metallic form which is essentially immobile and nontoxic in that form. The actual antimicrobial active ingredients are largely copper ions which would form gradually and only on the surface of the object constructed of the copper alloy depending on the environmental conditions. Although food uses are not being sought at this time, there are many registered agricultural, aquatic, and antifoulant uses of copper compounds that have resulted in concomitant exemptions from the requirement of a tolerance (40 CFR 180.1021). The major bases for the exemptions are that copper is an essential element, that the human body has controls over copper homeostasis to prevent high or low endogenous levels, and that no adverse systemic effects have been associated with copper compounds at any dose, including those high enough to cause gastric irritation. Similarly, adverse systemic effects are not induced via the dermal route of exposure to copper compounds and a few copper salts caused only very mild dermal irritation (Copper RED. 1/17/06. Joint HED/AD Human Health Assessment. D319683).

In terms of the many inert ingredients likely to be intentionally-added to make the various alloys, just as in the case of copper, each is present in the neutral, uncharged, or metallic form. Major ones may be [redacted]. The vast majority of the atoms of these elements will remain forever unexposed to the elements and untouched by human hands. Only small amounts of cations (positively charged ions) of these neutral metals will form, and, again, these will form only on the surface. Regardless, the major intentionally-added inerts in the proposed products are not of human health concern to the Agency.

Regarding potentially toxic inert ingredients, the Agency no longer has a concern for any ingredient in File Symbols 82012-G (Antimicrobial Copper Alloys Group III), 82012-U (Group IV), and 82012-L (Group V) as CDA voluntarily removed [redacted] from all alloys in these groups (and groups I and II as well).

Based on the 10/4/07 CSFs, [redacted] that could potentially be of concern to the Agency. These inerts of potential concern only apply to File Symbols 82012-R (Group I) and 82012-E (Group II): [redacted]

[redacted]

Humans have been exposed to numerous copper products and copper alloy touch surfaces for hundreds of years. All of these products included other metals as impurities and/or as alloying metals; in many cases, these products would have been fabricated long before we were aware of the toxicity of the cationic forms of some of the component metals. The Agency is certain that many of these older copper alloy products remain in use and that newer ones are being made [just without an antimicrobial claim.]

The bottom line is that many humans are likely to be currently exposed to the same neutral/metallic forms and ionic forms of the copper and intentionally-added inerts used to formulate the 275 copper alloys as we would be exposed to via our food, drinking water, existing touch surfaces, and any number of other exposure sources. The additional exposure of humans to the two or three potentially toxic inerts from use of Antimicrobial Copper Alloy Products is expected to be negligible.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

11/15/07

MEMORANDUM

SUBJECT: **Metallic Copper Alloys (P.C. Code 022501). EPA Reg. Nos. 82012-E, -G, -L, -R, and -U. Copper Alloy Products.** PRIA submission to determine data requirements and registerability of five groups of copper alloys proposed to be made into objects possessing antimicrobial activity. **D------, D------, D------, D------, and D------.**

FROM: William J. Hazel, Ph.D., Chemist
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

THROUGH: Norman Cook, Branch Chief
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

TO: Karen Leavy-Munk, Team 33
Regulatory Management Branch I
Antimicrobials Division (7510P)

INTRODUCTION:

The Copper Development Association, Inc. (CDA), a group of copper producers, brass mills, wire and cable companies, foundries, etc., has proposed to register five Antimicrobial Copper Alloys Groups comprised of 275 metallic copper alloys for which an antimicrobial claim has been made. These alloys will be shaped into objects that are frequently touched by human hands (touch surfaces) such as doorknobs, bed railings, IV poles, handles, knobs, etc. in health care facilities, community facilities, residential facilities, and limited playground equipment. Each alloy will be comprised of a commercial copper source (the active ingredient) and at least one other element (an intentionally-added inert) depending on the object and disposition thereof. The actual active antimicrobial

chemical species is the copper ion (largely Cu^{+2}) which would form gradually on the surface of the object constructed of the copper alloy depending on the environmental conditions. The inerts are generally metals that are added to impart certain properties to a given copper alloy such as strength, color, or corrosion resistance.

BACKGROUND:

Several communications, via teleconference or meeting, took place between CDA and EPA between April, 2004 and 4/18/07; the latter was a presentation of the antimicrobial properties of the copper alloys. The formal application for registration of the Antimicrobial Copper Alloys Groups I-V, dated 12/1/06, was made by Kelly Drye Collier Shannon on behalf of the CDA; at that time, there were a total of 317 different alloys. However, based partially on Agency concern over inerts of potential risk such as [redacted], this number of alloys was reduced to 275 when the Confidential Statements of Formula (CSFs) were revised on 10/4/07.

PROPOSAL:

The Agency has already agreed, in principle, that consideration for membership in one of the Antimicrobial Copper Alloy Groups would be given to all of the metallic copper alloys for which the CDA seeks registration. Membership in a specific Alloy Group is based on the percent by weight of copper in the alloy. The 10/4/07 CSFs break out as follows:

Group I contains 137 alloys at a nominal concentration of 96.2% Cu
Group II contains 54 alloys at a nominal concentration of 91.3% Cu
Group III contains 48 alloys at a nominal concentration of 82.6% Cu
Group IV contains 28 alloys at a nominal concentration of 73.0% Cu
Group V contains 8 alloys at a nominal concentration of 66.5% Cu

The 10/4/07 CSFs reflected removal of [redacted] from all Copper Alloy Groups and removal of [redacted] from Group II. The only remaining inerts of potentially toxic concern are [redacted] in Copper Alloys Group II and, in Group I, [redacted] CDA is planning to propose registration of a group of Antimicrobial Copper Alloys containing [redacted] at a later date.

CDA has made the following label claims: each alloy kills >99.9% of G^+ and G^- bacteria within 2 hr; each alloy kills >99.9% of G^+ and G^- bacteria over a 2-hr period; each alloy continuously kills >99% of G^+ and G^- bacteria over a 24-hr period; and each alloy kills >99% of G^+ and G^- bacteria after repeated contamination over a 24-hr period. AD has reviewed CDA's efficacy studies

generated on representative alloys from the five groups. There are still a number of issues remaining to be resolved between the AD and CDA regarding efficacy and labeling and between AD and OGC.

CONCLUSIONS:

The Agency has no concern over the major component of the five pending Antimicrobial Copper Alloy Groups, i.e., the metallic copper. The copper in the alloys is present in the metallic form which is essentially immobile and nontoxic in that form. The actual antimicrobial active ingredients are largely copper ions which would form gradually and only on the surface of the object constructed of the copper alloy depending on the environmental conditions. Although food uses are not being sought at this time, there are many registered agricultural, aquatic, and antifoulant uses of copper compounds that have resulted in concomitant exemptions from the requirement of a tolerance (40 CFR 180.1021). The major bases for the exemptions are that copper is an essential element, that the human body has controls over copper homeostasis to prevent high or low endogenous levels, and that no adverse systemic effects have been associated with copper compounds at any dose, including those high enough to cause gastric irritation. Similarly, adverse systemic effects are not induced via the dermal route of exposure to copper compounds and a few copper salts caused only very mild dermal irritation (Copper RED. 1/17/06. Joint HED/AD Human Health Assessment. D319683).

In terms of the many inert ingredients likely to be intentionally-added to make the various alloys, just as in the case of copper, each is present in the neutral, uncharged, or metallic form. Major ones may be [redacted] The vast majority of the atoms of these elements will remain forever unexposed to the elements and untouched by human hands. Only small amounts of cations (positively charged ions) of these neutral metals will form, and, again, these will form only on the surface. Regardless, the major intentionally-added inerts in the proposed products are not of human health concern to the Agency.

Regarding potentially toxic inert ingredients, the Agency no longer has a concern for any ingredient in File Symbols 82012-G (Antimicrobial Copper Alloys Group III), 82012-U (Group IV), and 82012-L (Group V) as CDA voluntarily removed [redacted] from all alloys in these groups (and groups I and II as well).

Based on the 10/4/07 CSFs, [redacted] that could potentially be of concern to the Agency. These inerts of potential concern only apply to File Symbols 82012-R (Group I) and 82012-E (Group II): [redacted]

[redacted]

Humans have been exposed to numerous copper products and copper alloy touch surfaces for hundreds of years. All of these products included other metals as impurities and/or as alloying metals; in many cases, these products would have been fabricated long before we were aware of the toxicity of the cationic forms of some of the component metals. The Agency is certain that many of these older copper alloy products remain in use and that newer ones are being made [just without an antimicrobial claim.]

The bottom line is that many humans are likely to be currently exposed to the same neutral/metallic forms and ionic forms of the copper and intentionally-added inerts used to formulate the 275 copper alloys as we would be exposed to via our food, drinking water, existing touch surfaces, and any number of other exposure sources. The additional exposure of humans to the two or three potentially toxic inerts from use of Antimicrobial Copper Alloy Products is expected to be negligible.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

February 6, 2007

MEMORANDUM

SUBJECT: Risk Assessment and Science Support Branch's (RASSB's) Review of PRIA Submissions for Copper Alloys Products

FROM: Norm Cook, Chief 2/6/07
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

TO: Dennis Edwards, Chief
Karen Leavy, PM Team 33
Marshall Swindell, PM 33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Chemical: Copper (metallic)

PC Code: 022501

Barcodes: D335571, D335579, D335584, D335590, D336370

Introduction and Background

RASSB is in receipt of five copper alloy products submitted for proposed registration: 82012-R (D335571), 82012-E (D335579), 82012-G (D335584), 82012-R (D335590), and 8201-L (D336370). Each package contains: registrant letter (12/1/06), labeling, and waiver requests for toxicology data. RASSB has reviewed each package and additionally reviewed the following documents:

- Minutes of October 4, 2006, pre-registration conference call regarding copper alloys
- Proposed copper alloys label
- Proposed Confidential Statement of Formula (CSF)
- Letter dated June 29, 2006 from Joseph J. Green, Council to the Copper Development Association, re: follow up to pre-registration Meeting: copper alloys

RASSB Comments

Based on a review of the above documents and discussions among RASSB scientists, we conclude that before initiating a full review of these submissions a number of critical issues need to be addressed by either the registrant, Product Manager (PM), or RASSB scientists. These issues are outlined below:

- What is the physical form of the proposed product(s),"Antimicrobial Copper Alloys": i.e., are they solid blocks, flat metal sheets, pellets?
- An earlier list of components and the corresponding percentages of components in the Confidential Statement of Formula (CSF) appears too broad to us. However, the present packages do not contain CSFs.
- The proposed labeling specifies the manufactured products which can be made from the "Copper Alloys" and includes a use restriction for "non-food contact surfaces" only. However, there are numerous listed articles which EPA considers as indirect food-contact sites: e.g., food carts, sinks, countertops, kitchen surfaces, ice/water dispensers. For such sites RASSB may need to perform dietary exposure/risk assessments; and for these and other sites RASSB has concerns with the presence of trace toxic metals in alloy compositions. *If food contact sites are intended for registration, then it appears that a tolerance or tolerance exemption is in order to support such uses (e.g., table tops, counter tops).*
- We note that other federal agencies and EPA Programs might also have concerns about the use of copper alloys in various use sites. For example, some of the uses listed in the pre-registration correspondence are consumer uses that might arguably come under the purview of Consumer Product Safety Commission (CPSC). Other uses (e.g., use in fabricated articles for medical/operating room equipment) might come under the purview of The Food and Drug Administration (FDA). In addition, it appears that some of the ingredients listed in the CSF may be considered "toxic substances" under the Toxic Substances Control Act (TSCA). Furthermore, disposal of these "non-food contact surfaces" might come under the purview of the Office of Solid Waste. Do we know whether the Copper Development Association has corresponded with any of these other EPA programs or federal agencies? At some point AD staff may want to contact staff in these other Agencies and EPA programs to determine whether they have any concerns about the use of copper alloys and other ingredients in the proposed surfaces.
- The Copper Development Association (CDA) as the proposed registrant is the market development and engineering/information services arm of the North American copper industry. (See their website copper.org). They are an entity representing multiple producers. Are there issues with this association being designated as a pesticide company registrant under FIFRA? For example, how will manufacturing site "establishment nos." be determined?
- We note that the labeling states that contact surfaces must be regularly cleaned, or sanitized, in order to assure antibacterial performance. This appears to be an unusual circumstance where the bacteriostatic surface (i.e., the pesticidal alloy) must be cleaned, or sanitized, (i.e., treated with an antimicrobial pesticide) in order to perform as claimed. Additionally, we believe that such regular cleaning, or sanitizing, may provide for increased release of alloy components.

- The present packages contain only waivers for toxicology data. Note that other data are normally required to support registration of the proposed use patterns (e.g., human exposure, residue chemistry). Waivers for these data requirements may also be appropriate.
- As we've indicated previously, RASSB has initially identified concerns with the use of [redacted] in the proposed products. However, with further review we may identify other alloy components with exposure, toxicological, or risk concerns. Considering this and RASSB's lack of metallurgical expertise, we believe that RASSB must discuss these metal alloy issues with other EPA Programs [redacted]

In conclusion, based on the submitted pre-registration and present PRIA documents, we have identified the above issues regarding the nature and premise of the copper alloy registrations. We believe that further discussion with the registrant, as well as with other EPA Programs and possibly with other federal agencies, are warranted before we can begin review of the submitted registration packages.

If you have any questions on the above, please contact Nader Elkassabany.

cc: D. Aviado
J. Chen
N. Elkassabany
P. Jennings
R. Petrie
N. Shamim
J. Tao

Decision #: 372578

DP #: (335585)

DATA PACKAGE BEAN SHEET

Date: 16-Jan-2007

* * * Registration Information * * *

Registration: 82012-G - ANTIMICROBIAL COPPER ALLOYS - GROUP III

Company: 82012 - COPPER DEVELOPMENT ASSOCIATION (CDA)

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828

Risk Manager Reviewer: Karen Leavy KLEAVY

Sent Date: _____ Calculated Due Date: 22-Sep-2007 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A50) NEW USE;NON-FOOD;INDOOR FIFRA SEC 2(MM) USES;

Ingredients: 022501, Copper (metallic)(82.6%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 16-Jan-2007 Due Back: _____

DP Ingredient: 022501, Copper (metallic)

DP Title: _____

CSF Included: ○ Yes ● No Label Included: ● Yes ○ No Parent DP #: _____

270
1 89

Assigned To		Date In	Date Out	
Organization:	AD / PSB	1/14/07		Last Possible Science Due Date: 03-Jul-2007
Team Name:	EET	1/16/07		Science Due Date: 7/9/07
Reviewer Name:	[illegible] 3/8/07	~~1/17/07~~		Sub Data Package Due Date: 7/24/07
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

Printed on Page 2

* * * Data Package Instructions * * *

Please review the submitted efficacy studies and summary(MRID#s 469993-04, 469993-05, 469993-06, 469993-07, 469993-08, 469993-09, 469993-10, 469993-11, 469993-12, and 469993-13. PRIA, Action Code A50, Admin Due Date 9/22/07, EET Due Date 4/22/07

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Copper Development Association, 260 Madison Ave., NY, NY 10016-2401 212-251-7234	
Active Ingredient(s) and/or representative test compound(s)	**Date**
Copper (metallic)	December 1, 2006
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)	**Product Name**
Indoor, non-food	Antimicrobial Copper Alloys Group III

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☑ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

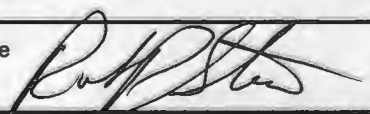
I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
	Dec. 1, 2006	Robert R. Stewart, Ph.D.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date December 1, 2006	EPA Reg No./File Symbol	Page 1 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group III	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	This submission	Copper Development Association	Own	
830.1600	Description of Materials Used to Produce Product	This submission	Copper Development Association	Own	
830.1620	Description of Production Process	This submission	Copper Development Association	Own	
830.1650	Description of Formulation Process	This submission	Copper Development Association	Own	
830.1670	Discussion of Formation of Impurities	This submission	Copper Development Association	Own	
830.1700	Preliminary Analysis	This submission	Copper Development Association	Own	
830.1750	Certified Limits	This submission	Copper Development Association	Own	
830.1800	Enforcement Analytical Method	This submission	Copper Development Association	Own	
830.1900	Submittal of Standards	This submission	Copper Development Association	Own	

Signature	Name and Title	Date
11-30-06	Robert R. Stewart, Ph.D., Regulatory Agent	Dec. 1, 2006

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date December 1, 2006	EPA Reg No./File Symbol	Page 2 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group III	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6302	Color				Not required OPPTS 830.1000
830.6303	Physical State	This submission	Copper Development Association	Own	
830.6304	Odor				NA Not required OPPTS 830.1000
830.6313	Stability to Temperature, Metals, and Metal Ions				Not required OPPTS 830.1000
830.6314	Oxidation/Reduction	This submission	Copper Development Association	Own	
830.6315	Flammability	This submission	Copper Development Association	Own	
830.6316	Explodability	This submission	Copper Development Association	Own	
830.6317	Storage Stability	This submission	Copper Development Association	Own	
830.6319	Miscibility	This submission	Copper Development Association	Own	
830.6320	Corrosion Characteristics	This submission	Copper Development Association	Own	
830.6321	Dielectric Breakdown Voltage	This submission	Copper Development Association	Own	
830.7000	pH	This submission	Copper Development Association	Own	
830.7050	UV/Visible Absorption				Not required OPPTS 830.1000
830.7100	Viscosity	This submission	Copper Development Association	Own	

Signature	Name and Title	Date
	Robert R. Stewart, Ph.D., Regulatory Agent	Dec. 1, 2006

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date December 1, 2006	EPA Reg No./File Symbol	Page 3 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group III	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7200	Melting Point/Melting Range				Not required OPPTS 830.1000
830.7220	Boiling Point/Boiling Range				Not required OPPTS 830.1000
830.7300	Density/Relative Density/Bulk Density	This submission	Copper Development Association	Own	
830.7370	Dissociation Constants in Water				Not required OPPTS 830.1000
830.7550	Partition Coefficient (n-octanol/water)				Not required OPPTS 830.1000
830.7840	Water Solubility				Not required OPPTS 830.1000
830.7950	Vapor Pressure				NA Not required OPPTS 830.1000

Signature	Name and Title	Date
Robert R. Stewart	Robert R. Stewart, Ph.D., Regulatory Agent	Dec. 1, 2006

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date December 1, 2006	EPA Reg No./File Symbol	Page 4 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group III	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute Oral Toxicity - Rats	This submission	Copper Development Association	Own	
870.1100	Acute Oral Toxicity - Mice	This submission	Copper Development Association	Own	
870.1200	Acute Dermal Toxicity	This submission	Copper Development Association	Own	
870.1300	Acute Inhalation Toxicity	This submission	Copper Development Association	Own	
870.2400	Acute Eye Irritation	This submission	Copper Development Association	Own	
870.2500	Acute Dermal Irritation	This submission	Copper Development Association	Own	
870.2600	Skin Sensitization	This submission	Copper Development Association	Own	
870.3150	90-Day Oral Toxicity - Dogs	This submission	Copper Development Association	Own	
870.3465	90-Day Oral Toxicity - Rats	This submission	Copper Development Association	Own	
870.3700	Prenatal Developmental Toxicity - Rabbits	This submission	Copper Development Association	Own	
870.3700	Prenatal Developmental Toxicity - Rats	This submission	Copper Development Association	Own	
870.3800	Reproduction and Fertility Effects - 2 Gen	This submission	Copper Development Association	Own	
870.4100	Chronic Feeding, Dog	This submission	Copper Development Association	Own	
870.4100	Chronic Feeding, Rat	This submission	Copper Development Association	Own	
870.5100	Bacterial Reverse Mutation (Ames) Test	This submission	Copper Development Association	Own	
870.	Other Mutagenicity	This submission	Copper Development Association	Own	
870.7485	Metabolism and Pharmacokinetics - Rat	This submission	Copper Development Association	Own	

Signature	Name and Title	Date
	Robert R. Stewart, Ph.D., Regulatory Agent	Dec. 1, 2006

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20461. Do not send the form to this address:

DATA MATRIX

Date December 1, 2006	EPA Reg No./File Symbol	Page 5 of 5
Applicant's/Registrant's Name & Address Copper Development Association, 260 Madison Ave. NY, NY 10016	Antimicrobial Copper Alloys Group III	

Ingredient Copper (Metallic)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.2000	Hard Surface Sanitizer Assay	This submission	Copper Development Association	Own	
810.2000	Residual Self-sanitizer Assay	This submission	Copper Development Association	Own	
810.2000	Repeat Challenge Assay	This submission	Copper Development Association	Own	

Signature	Name and Title	Date
Robert R. Stewart	Robert R. Stewart, Ph.D., Regulatory Agent	Dec. 1, 2006

171

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [✓] Registration
- [ ] Amendment
- [ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
82012-G	Edwards/Swindell	[✓] None [ ] Restricted
4. Company/Product (Name) Antimicrobial Copper Alloys - Group III	**PM#** 33	
5. Name and Address of Applicant *(Include ZIP Code)* Copper Development Association 260 Madison Avenue New York, New York 10016-2401 [ ] *Check if this is a new address*	**6. Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in repsonse to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I end Section II.)

The submitter has determined that the PRIA category for this application is A50 and the fee will be $10,500.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [✓] No	[ ] Yes [✓] No	[ ] Yes [✓] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [✓] Other (Specify) none
** Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[✓] Label [ ] Container	NA - no container	[✓]

6. Manner in Which Label is Affixed to Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [✓] Other Attached to Bill of Lading

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Robert R. Stewart, Ph.D.	Regulatory Consultant	202-828-8983

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received
[signature]	Regulatory Consultant	(Stamped)
4. Typed Name Robert R. Stewart, Ph.D.	**5. Date** December 1, 2006	

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

KELLEY DRYE
COLLIER SHANNON

Joseph J. Green
Special Counsel
Kelley Drye Collier Shannon
JGreen@KelleyDrye.com

December 1, 2006

Via Hand Delivery and Electronic Mail

Antimicrobial Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
ATTN: Dennis Edwards, Branch Chief,
Regulatory Management Branch I

Re: Application for Registration of Antimicrobial Copper Alloys Groups I-V

Dear Antimicrobial Division:

On behalf of the Copper Development Association (CDA), today we are filing five applications for the registration of certain copper-containing alloys as antibacterial products for use in a variety of settings, including health care facilities, public buildings, and residences. The set of five applications – for "Antimicrobial Copper Alloys" Groups I through V – is the product of extensive discussions and cooperation over the past two-and-a-half years with representatives of EPA's Antimicrobial Division, including Dennis Edwards, branch chief of Regulatory Management Branch I. Those discussions resulted in an agreement to file the five applications, which altogether cover approximately 317 different alloys that contain copper in amounts ranging from 64.1% to over 99%.[1] A brief overview of the discussions between CDA and EPA is provided below to clarify some of the issues that arose during these discussions regarding the registration process for these alloys.

Efficacy Testing

In April 2004, CDA first approached the agency about obtaining registration for over 300 alloys that contain copper in amounts for which antimicrobial efficacy is demonstrated. After that initial meeting, subsequent discussions in November 2004 and March 2005 resulted in an agreement that five representative antimicrobial copper alloys would be selected for efficacy testing using three different test methodologies, which are described below and in more detail in

[1] Copper alloys that contain [redacted] in amounts at or above 0.1% will be covered by a sixth application that will be filed in the near future.

the accompanying registration application. During these meetings, it was also agreed that, for each type of testing, the "basic" efficacy tests would be performed on three independent lots of each of the five representative copper alloys against *Staphylococcus aureus* and *Enterobacter aerogenes*. Similarly, "supplemental" efficacy tests would be performed on two independent lots of each of the five representative copper alloys against *Staphylococcus aureus* (a methicillin-resistant isolate), *Pseudomonas aeruginosa* and *Escherichia coli* O157:H7. The three sets of efficacy testing included:

(1) A modified version of the standard test method for non-food contact sanitizers (the "Test Method for Efficacy of Copper Alloy Surfaces as a Sanitizer[2]") to demonstrate that the copper alloy surfaces kill greater than 99.9% of bacteria within two hours.

(2) A second protocol to show that the copper alloy antimicrobial effect is durable, and that repeated wiping of the surface does not impair effectiveness. The test protocol – "Test Method for Residual Self-Sanitizing Activity of Copper Alloy Surfaces" – follows the EPA Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard Nonporous Surfaces.

(3) A third protocol to demonstrate continual antibacterial activity after multiple reinoculations over a 24-hour period. The test protocol – "Test Method for the Continuous Reduction of Bacterial Contamination on Copper Alloy Surfaces" – is modeled upon the basic method described in the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-food Contact Surfaces (ASTM E 1135-03). The performance criteria for this protocol is a greater than 99% reduction after all reinoculations over 24 hours.

Communications with EPA, including Nancy Whyte and Marshall Swindell, have indicated that the test protocol methodologies have been approved.

The GLP testing described above was conducted during 2005-2006 on five representative copper alloy formulations[3]: (1) Alloy C11000 (~99.9% copper); (2) Alloy C51000 (~94.8%

[2] While the term "sanitizer" is used as part of the name of the test protocol, it is understood that "sanitizer" claims are not supported by the efficacy testing data.

[3] The five tested alloys represent typical formulations from five of the most common "families" of copper alloys: (1) "Coppers" - containing over 99% copper; (2) "Bronzes" – containing ~85-95% copper with [redacted] typically as the primary alloying element; (3) "Copper-

(...continued)

copper); (3) Alloy C70600 (~88.6% copper); (4) Alloy C26000 (~70% copper); and (5) Alloy 75200 (~65% copper).

Registration Groups and Product Chemistry

During meetings in June and July 2006, pending formal review of the application, EPA agreed that it would be unrealistic to register each of the 300+ alloys for which CDA seeks registration. The agency also recognized that the five tested alloys provide representative data to support a limited number of registrations, each covering a group of alloys that contain copper within the range of the tested alloys. In order to narrow the range of copper content covered by a single registration, EPA requested CDA to develop several alloy groups, defined by copper content, for registration purposes. In our October 2006 conference call, the agency agreed with CDA that the following five alloy groups were appropriate for registration: (1) Group I: alloys containing 95.2-99.99% copper (171 alloys); (2) Group II: alloys containing 87.2-95.1% copper (58 alloys); (3) Group III: alloys containing 78.0-87.1% copper (50 alloys); (4) Group IV: alloys containing 68.2-77.9% copper (29 alloys); and (5) Group V: alloys containing 64.1-68.1% copper (9 alloys).

Alloy C11000 and C51000 represent the alloys in Antimicrobial Copper Alloy Group I. Alloy C70600 represents the alloys in Antimicrobial Copper Alloy Group II. Alloy C26000 represents the alloys in Antimicrobial Copper Alloy Groups III and IV. And finally, Alloy C75200 represents the alloys in Antimicrobial Copper Alloy Group V. The efficacy testing for each Antimicrobial Copper Alloy group was performed with the alloy having a copper content at the Lower Certified Limit for that group.

Accordingly, CDA is submitting applications for the registration of the five copper alloy groups described above. The Confidential Statement of Formula (CSF) for each alloy group identifies numerous inert ingredients that may be present with copper in the various alloy formulations; each alloy will contain only some of the inert ingredients identified in the CSF. The Lower Certified Limit for each inert alloy ingredient is set at [redacted] In order to have the ingredients on the CSF add up to 100%, as required by EPA, a line in the CSF has been added that represents all of the metals in sum. Each application also specifies the standard

(...continued)
[redacted] – containing ~65-95% copper with [redacted] as the primary alloying element; (4) [redacted] – containing ~60-96% copper with [redacted] as the primary alloying element; and (5) [redacted] – containing ~43-74% copper with [redacted] as the primary alloying elements (there is little to no [redacted] in these alloys; the [redacted] in the family name comes from the appearance of the alloy).

industry classification code (Uniform Numbering System, or UNS code) that defines the formula of each of the alloys covered by the registration. For the label, the arithmetic average of the upper and lower limits of the copper content for each registration group is used as the nominal concentration. The label that will accompany the copper alloy product on the market will specify the exact percentage of copper in that product, according to its UNS code.

Claims

For each of the five Antimicrobial Copper Alloy groups, the data from the efficacy testing support the following claims:

(1) This surface kills greater than 99.9% of bacteria* within 2 hours of exposure.

(2) This surface kills greater than 99.9% of bacteria* for 24 hours.

(3) This surface remains effective in killing greater than 99.9% of bacteria* within two hours, even after repeated wet and dry abrasion and re-contamination.

(4) This surface provides continuous, ongoing and persistent antibacterial* action, achieving 99.9% reduction within two hours of exposure.

(5) This surface impedes the growth and build-up of bacteria* within two hours of exposure.

(6) This surface kills greater than 99% of bacteria* within two hours after repeated contamination over a 24-hour period.

* Testing demonstrates effective antibacterial activity against *Staphylococcus aureus*, *Enterobacter aerogenes*, Methicillin Resistant *Staphylococcus aureus* (MRSA), *Escherichia coli* O157:H7, and *Pseudomonas aeruginosa*.

These claims were reviewed and refined during a series of meetings and discussions with EPA during 2006, including our most recent conference call on October 4, 2006.

During our discussions with EPA, the agency requested that CDA provide a statement regarding the potential antimicrobial activity of the inert ingredients contained in various copper alloy formulations. To our knowledge, none of the inert ingredients, with the exception of [redacted], is a recognized antimicrobial agent. CDA has conducted testing on three of the inert ingredients found in certain copper alloys – [redacted] – and that they demonstrate no

meaningful antimicrobial activity. With respect to [redacted] none of the five representative alloys for which GLP efficacy testing was conducted contained [redacted] Accordingly, the conclusions regarding the antimicrobial efficacy of copper are unaffected by the potential presence of [redacted] in a limited number of other Antimicrobial Copper Alloys. To the extent that [redacted] has antimicrobial activity in these alloy formulations, the effect would simply add to the effectiveness of the product that is overwhelmingly attributable to the high percentage of copper.

Product Uses

The proposed label for each registration group specifies a range of products that may be manufactured from copper alloys and marketed with appropriate antibacterial claims. Appropriate uses include a variety of touch surfaces in healthcare facilities, public and commercial buildings, and residences. No food contact applications are included. A detailed list of potential uses for Antimicrobial Copper Alloys is provided in the proposed labels.

Toxicity

Copper alloys have been widely used in numerous applications involving direct human contact throughout human history with no adverse impact on health or the environment. Based on this history and existing knowledge (including from the agency's recently completed Reregistration Eligibility Document for copper) regarding the potential toxicity (or lack thereof) of copper, CDA is seeking a waiver of the toxicity data requirements for registration.

The argument for waiving toxicity studies for Antimicrobial Copper Alloys identifies four basic supporting rationales: (1) copper is a ubiquitous naturally occurring metal that is exempt from the requirement of a tolerance for most uses; (2) there is a lack of potential for oral, inhalation, ocular, or prolonged dermal exposure to copper alloy products; (3) there is a lack of biological availability to the chemical components of copper alloys due to chemical structure; and (4) copper alloys have a long history of safe use in the same types of end use products proposed for registration.

For these reasons, CDA also contends that it is unnecessary to include on the label sections dealing with Precautionary Statements or Environmental Hazards.[4] Similarly, the lack of toxicity associated with Antimicrobial Copper Alloys renders unnecessary the need for the "Keep Out of Reach of Children" statement or any signal words, such as "Caution."

[4] Antimicrobial Copper Alloys pose no environmental hazard as there is limited opportunity for environmental exposures or releases to the environment during product use or transport.

With regard to the potential inert ingredients in copper alloys, in our discussions EPA has asked about the potential toxicological effects attributable to two specific alloying elements found in a limited number of copper alloys – [redacted], which is present at levels up to [redacted] in 36 (of the 317) alloys under review, is exclusively in the relatively non-toxic metallic form; none is present as [redacted] is present at no more than [redacted] in the five alloys in which it is contained and, therefore, presents a limited risk of exposure. Potential exposure is further limited by the fact that the alloying process tightly binds the vast majority of the constituent elements within the alloy matrix. Accordingly, neither [redacted] present a risk to users of copper alloys.

Finally, it was agreed with the agency that the registration of copper alloys containing lead would proceed under a separate track, after further discussion of how to address any potential health risks associated with the presence of that metal is certain alloy formulations. CDA intends to seek registration of such alloys in the near future.

* * * *

We appreciate the agency's cooperation over the past two-plus years in addressing the registration issues associated with Antimicrobial Copper Alloys and believe that the process has resulted in a set of application packages that hopefully will expedite approval of the registrations. If there are any questions regarding the applications, please contact Bob Stewart of Technology Sciences Group Inc. at 202.828.8963 or me at 202.342.8849 or JGreen@KelleyDrye.com.

Very truly yours,

Joseph J. Green
Counsel to the Copper Development Association

cc: Marshall Swindell, Team Leader

VOLUME 1 OF 14 OF SUBMISSION

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Copper Development Association Inc.
260 Madison Avenue
New York, NY 10016

REGULATORY ACTION:

Application to register the *Antimicrobial Copper Alloys Group III*

PRIA Category A50: New use, Non-food, indoor, FIFRA section 2 (mm) uses

TRANSMITTAL DATE:

December 1, 2006

LIST OF SUBMITTED STUDIES:

MRID NUMBER	VOLUME NUMBER	EPA STUDY TITLE	GUIDELINE NUMBER
	1 of 14	(Transmittal Document)	----------
	2 of 14	*Antimicrobial Copper Alloys Group III* Product Properties- Group A	830.1550 – 830.1900
	3 of 14	*Antimicrobial Copper Alloys Group III* Toxicology Data Waiver Requests	870.1100 – 870.2600 870.3150 – 870.5375
	4 of 14	Administrative Volume: Summary of Efficacy Testing Results For Five Antimicrobial Copper Alloys	Not applicable
	5 of 14	*Antimicrobial Copper Alloys Group III* Test Method for the Continuous Reduction Of Bacterial Contamination on Copper Alloy Surfaces – Project No. A03207	810.2000
	6 of 14	*Antimicrobial Copper Alloys Group III* Test Method for the Continuous Reduction Of Bacterial Contamination on Copper Alloy Surfaces – Project No. A03208	810.2000

7 of 14	*Antimicrobial Copper Alloys Group III* Test Method for Efficacy of Copper Alloy Surfaces as a Sanitizer – Project No. A03317	810.2000
8 of 14	*Antimicrobial Copper Alloys Group III* Test Method for Efficacy of Copper Alloy Surfaces as a Sanitizer – Project No. A03318	810.2000
9 of 14	*Antimicrobial Copper Alloys Group III* Test Method for Residual Self-Sanitizing Activity of Copper Alloy Surfaces - Project No. A03425	810.2000
10 of 14	*Antimicrobial Copper Alloys Group III* Test Method for Residual Self-Sanitizing Activity of Copper Alloy Surfaces - Project No. A03505	810.2000
11 of 14	*Antimicrobial Copper Alloys Group III* Test Method for Efficacy of Copper Alloy Surfaces as a Sanitizer – Project No. A03615	810.2000
12 of 14	*Antimicrobial Copper Alloys Group III* Test Method for the Continuous Reduction Of Bacterial Contamination on Copper Alloy Surfaces – Project No. A03616	810.2000
13 of 14	*Antimicrobial Copper Alloys Group III* Test Method for Efficacy of Copper Alloy Surfaces as a Sanitizer – Project No. A03844	810.2000
14 of 14	*Antimicrobial Copper Alloys Group III* Test Method for the Continuous Reduction Of Bacterial Contamination on Copper Alloy Surfaces – Project No. A03845	810.2000

COMPANY NAME: Copper Development Association Inc.

COMPANY OFFICIAL:

Robert Stewart, Regulatory Consultant

COMPANY CONTACT:

Robert Stewart, Regulatory Consultant
Technology Sciences Group, Inc.
1150 18th Street, N.W. Ste.1000
Washington, DC 20036
(202) 828-8963

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 5, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-372578
EPA File Symbol or Registration Number: 82012-G
Product Name: ANTIMICROBIAL COPPER ALLOYS - GROUP III
EPA Receipt Date: 05-Dec-2006
EPA Company Number: 82012
Company Name: COPPER DEVELOPMENT ASSOCIATION (CDA)

JOSEPH J. GREEN
COLLIER SHANNON SCOTT, PLLC
COPPER DEVELOPMENT ASSOCIATION (CDA)
3050 K STREET, N.W., SUITE 400
WASHINGTON, DC 20007-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A50

NEW USE;NON-FOOD;INDOOR FIFRA SEC 2(MM) USES;

Please remit payment in the amount of: $ 10,500 to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 360277
Pittsburgh, PA 15251

By Courier:
U.S. EPA Washington Finance Center
Pesticide Registration Service Fee
C/O Mellon Client Service Center
500 Ross Street, Room 670
Box 360277
Pittsburgh, PA 15251-6277
Attn: EPA Module Supervisor
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how th request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

By USPS:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

By Courier:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1801 S. Bell St.
Arlington, VA 22202

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 45 days, the Agency will presume that you no longer want to pursue this action. The Agency will then initiate a process that may result in administrative withdrawal of this action.

If you have any questions, please contact the Pesticide Registration Service Fee

Ombudsman at (703) 308-6432.

Sincerely,

Teresa Downs

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{802171v~

This package includes the following

- [•] New Registration
- [ ] Amendment

[✓] Studies? Fee Waiver?

[ ] volpay % Reduction: ___

for Division

- (•) AD
- ( ) BPPD
- ( ) RD

Risk Mgr. 33

Receipt No. S-	802171
EPA File Symbol/Reg. No.	82012-G
Pin-Punch Date:	12/5/2006

[ ] This item is NOT subject to FFS action.

Action Code:

Requested: A50

Granted: A50

Amount Due: $ 10,500.00

Parent/Child Decisions:

Reviewer: Heyward/Whitaker/Swindell Date: 12/5/06

Remarks: